ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING

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Submitted By

DR KARAN SINGH

DEPARTMENT OF PLASTIC AND RECONSTRUCTIVE SURGERY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA, PUNJAB

DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled "**ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING**" submitted towards partial fulfillment of the requirements for the award of **M.Ch in Plastic and Reconstructive surgery** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Rajinder Kumar Mittal**, Professor and Head, Department of Plastic and Reconstructive Surgery and **Dr. Sheerin Shah**, Associate Professor, Department of Plastic and Reconstructive Surgery. No part of this thesis has formed the basis for the award of any degree previously.

_____

Dr. Karan Singh
Department Of Plastic &
Reconstructive Surgery
Dayanand Medical College & Hospital,
Ludhiana, Punjab

Date:

Place:

CERTIFICATE OF SUPERVISORS

This is to certify that the work incorporated in this thesis entitled "**ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING"** has been carried out by **Dr. Karan Singh** under our direct supervision. The data incorporated in this thesis is original and genuine and has been carried out by the candidate himself.

Signature of Supervisor

Dr. Rajinder Kumar Mittal
Professor & Head
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Signature of Co-Supervisor

Dr. Sheerin Shah
Associate Professor
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Date:

ENDORSEMENT BY THE HEAD OF THE INSTITUTE

This is to certify that the thesis entitled "**ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING"** is a bonafide research work done by **Dr. Karan Singh** under the supervision of **Dr. Rajinder Kumar Mittal**, Professor and Head, Department of Plastic and Reconstructive Surgery and **Dr. Sheerin Shah**, Associate Professor, Department of Plastic and Reconstructive Surgery in this institution.

Principal

Dr. Sandeep Puri
Principal
DMC&H, Ludhiana

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Signature

Dr. Karan Singh
Department of Plastic and Reconstructive Surgery,
Dayanand Medical College & Hospital,
Ludhiana, Punjab - 141001

Date:

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Dedicated

to

my Family

&

Teachers

LIST OF ABBREVIATIONS

ALT	Antero Lateral Thigh Flap
DI	Distally Ischemic
LD Flap	Latissimus Dorsi Flap
PMMC Flap	Pectoralis Major Myocutaneous Flap
SAS	Same As Surrounding

ABSTRACT

Introduction: Reconstruction using free flaps has become a reliable technique. Pedicle thrombosis is a dreaded complication, and the earlier diagnosis of such a complications has higher surgical salvage rate. Clinical monitoring remains the most useful but make late and unreliable diagnosis. Numerous studies aimed to find ideal monitoring techniques for free flaps. Actually the most efficient ones often deal with expensive and invasive techniques. In this study, we suggest an efficient, simple, cheap technique to detect arterial or vein thrombosis after free flaps vessels anastomosis.

Aim of study: The aim of present study is cappillary blood lactate moitoring as predictor of flap survival.

Materials & Methods: A prospective study will be conducted on around 30 patients admitted in Department of plastic surgery, Dayanand Medical Collage and Hospital, Ludhiana who will undergo any type of flap coverage for various defects, Flaps that do not bleed on pinprick will be excluded from the study. All diabetic and critically ill pt will be excluded from the study. Blood lactate measurement will be done using the same lactometer device with a drop of blood after pin prick from free flap and for pedicled flap from distal end of the flap. Blood lactate measurement will be done at 0, 1, 3, 6, 12, 48 hrs after surgery.

Clinical significance: This will lead to the development of simple, rapid and easy method for flap monitoring without requiring complex appratus.

Keywords: Free flap; Arterial thrombosis; venous thrombosis; Lactate; Complication.

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(Dr. Karan Singh)

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INTRODUCTION

Flap plays an important role in reconstructive surgery. Flap reconstruction is used for coverage of defects throughout the various parts of the body. This type of reconstruction requires a patient in good general condition. The free flap failure rate varies between 2% and 5%. There are multiple causes: infection, dehiscence of sutures, compression or vascular thrombosis. Vascular thrombosis are the most frequent complications and represents 15-73% [(1)].

The free flap survival rate has been stabilizing at 94–99%, but the rate of salvage surgery in treating impaired blood flow is poor at 34–73% [(2)]. Over time, impaired blood flow becomes irreversible, sustaining to loss of flap or distal necrosis of flap. Also Leaving impaired blood flow untreated can result in serious complications such as massive bleeding due to ruptured sutures or spread of infection

The goal of postoperative flap monitoring is to detect microvascular complications before permanent injury to the flap occurs and thus maximize the potential for salvage. Vascular compromise usually occurs within 48 hours of surgery [(3)]. Early detection of compromised perfusion provides options to correct problems and to save a flap. Various methods of measuring flap viability have been proposed to recognise flap compromise as soon as possible. Ideal flap monitoring system should be simple, reliable, reproducible and sensitive [(4)].

None of the presently available monitoring system fulfils all the requirements. Various techniques available for flap monitoring are doppler ultrasonography of the vascular pedicle [(5)], measurement of tissue oxygenation [(6)], analysis by microdialysis **[(7)]**, use of intra-arterial or intravenous catheters [(8)], and quantitative spectral imaging **[(3)]**. These methods require complex and expensive apparatus.

Clinical observation is the gold standard method of assessing the flap viability [(9)]. It is based on color, capillary refill time and local heat of the flap. Surgeons rely on physical examination to assess the vascularity of

flaps by measuring temperature, color, capillary refill and pin prick. Clinical assessment of the flap is subjective parameter and may be faulty if the surgical team lacks experience or if other non-ideal factors such as inadequate lightning or visualization difficulties are present.

Assessment of flap skin color and its comparison with adjacent normal skin is a valuable indicator of flap viability, capillary refill time is an adjunct to skin colour assessment in flap monitoring. Colour of flap same as surrounding skin and capillary refill time <3 secs indicate a healthy flap. A pale colour and delayed capillary refill indicates arterial insufficiency, whereas a dusky colour with brisk capillary refill represents venous congestion.

The most commonly used method is the color of blood that oozes from the flap on pin prick. Bright pink oozing represents a healthy flap, whereas dark purplish oozing reflects compromised perfusion of flap. Surface temperature monitoring is another commonly used method to assess flap viability [(10)]. Main drawback of surface temperature monitoring is the subjective variability and it also varies with environmental factors.

Measurements of various expects of flap metabolism have been utilized for monitoring of flaps. In different methods measurement of transcutaneous oxygen tension is one of the oldest methods of assessing flap viability [(11)]. This method is, however subject to many other systemic factors affecting oxygen transport and tissue oxygenation. Doppler ultrasonography is a simple and commonly used method for evaluation of blood flow in flaps [(5)].

Doppler probe can be used to detect flow· of in-depth vessels. But it cannot differentiate between the signals coming from adjacent normal vessels deep to the flap. Laser Doppler study is another method which measures skin blood flow and can be used for non-invasive, continuous monitoring of skin flaps [(3)]. Major limitations with this technique are sensitivity to position, sensitivity to temperature, shallow penetration and small sample area which limits its clinical utility.

Assessment of skin perfusion using fluorescein dye is another method of assessing the flap viability [12]. But the Tissue that is adequately perfused fluoresces well under ultraviolet lamp, whereas inadequately perfused tissue is not seen with the ultraviolet lamp. This method usually underestimates the amount of tissue that will ultimately survive. Serial use of this method is also cumbersome. Continuous pH monitoring of a flap is another method of assessing metabolic function. Anaerobic metabolism in flap causes rapid fall in pH due to vascular compromise.

Recent reports have suggested that blood flow abnormalities can possibly be detected early through measurement of blood glucose and lactate values [14, 15]**.** This method of assessment of flap viability is simple, cost effective and requires little special equipment. It is more objective than traditional methods of flap monitoring such as observing colour, turgor or pin prick examination. Thus, the present study was conducted to determine intra-flap blood lactate values measured with a simple instrument could detect impaired blood flow during reconstruction and during post-op monitoring of free flaps.

AIM AND OBJECTIVES

The present investigative study aims at-

1. To evaluate the flap on the basis of clinical examination which includes the color change, capillary refill, bleeding characteristics and temperature of flap.
2. To study flap capillary blood lactate monitoring as predictor of flap survival.

REVIEW OF LITERATURE

Flap reconstructions are today a common procedure, whatever the type of flap. Despite this evolution, the success rate never reaches 100% in large series [16], mainly due to pedicle complications such as thrombosis, extrinsic compression, or kinking effects [17]. This failure rate remains a concern and could lead to serious functional impairment. Moreover, it is widely accepted that the prognosis of such complications is improved if they are treated early [2].

The majority of these complications occurred within the first 24 postoperative hours. The salvage rate of postoperative vascular complications is between 0 and 100% [18]. The consequences of failure are often severe: higher risk of death, delay of combination therapy (radiotherapy, chemotherapy), functional sequelae, aesthetic results, psychological and social effects. The success rate is greater when salvage surgery is early [19]. It is therefore essential to detect as soon as possible arterial or venous thrombosis.

Despite rapid development in the field of reconstructive surgery, one core issue that persists to this date is the inability to accurately predict the viability of a flap. Although many attempts have been made to elucidate elaborate as well as simple adjuncts to aid the surgeon in his decision making, the ideal technique remains to be found.

Creech and miller [20] proposed that the ideal technique for assessment of flap viability should fulfill the following criterion:

Simple and harmless to the patient.

Rapid, repeatable, reliable, recordable and rapidly responsive.

Accurate and inexpensive.

Objective and applicable to all kind of flaps.

Equipped with a simple display that could alert relatively in experienced personnel to the development of circulatory impairment.

The most common technique used to check for flap viability is “Clinical examination”. These may include all or a combination of the following:

Colour

Turgor

Temperature

Capillary refill time

Bleeding following pin prick.

Although these methods are cheap and repeatable, they have certain limitations. The appreciation of colour, for example, is dependent on ambient lighting conditions. The colour of the donor site may be different from the recipient site as well. Skin turgor is affected by hydration status. Surface temperature is dependent on many factors including blood flow and changing metabolic rate of the underlying muscle. Capillary refill time too has a wide variation amongst its users due to little standardization. Hence, these techniques have to be supplemented by other more objective and reliable methods.

In addition to clinical examinations, surface or implantable doppler, spectrophotometry, laser Doppler, tissue oximetry, and tissue pH may be used to screen pedicle impairments. Even if clinical examination has many drawbacks, these screening tests tend to be expensive and complex procedures. Among them, microdialysis [17, 21] retained our attention. Simplification could be done by measuring capillary lactate. This procedure is evaluated in the present study.

The evaluation method for flap blood flow often relies on the visual impression of a physician or co-medical practitioner. Patients who have undergone head and neck reconstruction often have a free flap in the oral cavity, which is difficult to observe, so visual evaluation of blood flow is difficult. Therefore, persons who evaluate blood flow need more training. This may be possible in a large facility but is impossible in a small facility. If standard parameters exist that reflect flap blood flow, we believe that diagnostic capability will not differ between institutions. In this study, we will identify numerical values that reflect flap blood flow.

Among the numerous evaluation methods for flap blood flow, a method that measures intra-flap glucose and lactate values using microdialysis has been devised [14, 22]. Microdialysis involves the use of embedded catheter in the flap tissue (eg, skin, muscle, or fat) to measure the target substance and can be used for buried flaps; however, it requires professional expertise. Currently, the primary methods indicated for evaluating flap blood flow are visual examination and clinical findings such as those from the pinprick test [23]. However, these methods vary widely depending on the evaluator's experience and level of objectivity.

Furthermore, the pinprick test can only be used for accessible flaps [24]. Ideally, blood flow evaluation should be simple and objective with no variance due to occupation or experience. Despite various studies on flap blood flow evaluation methods, [25-27] no standard has been established yet because the methods use expensive instruments or ones that are complicated to operate. Recent reports have suggested that blood flow abnormalities can possibly be detected early through measurement of blood glucose and lactate values [15].

Several reports mentioned below described the effects of blood flow obstruction on lactate values:

Benjamin E. Cohen et al (1982) has done a experimental study on glucose metabolism in rat abdominal skin flaps [28]. To diminish the circulation in flaps superficial inferior epigastric artery was ligated after flap elevation in standard flaps of approx 5x3 cm whole of tissue survived but in larger flaps of 11x3 cm. Distal 4x5 cm of flap get necrosed. Skin biopsy has been taken from the flaps during the first 3 days after flap elevation. There is marked increase in glucose consumption and lactate production in flaps compared to normal skin. Increase in glucose consumption by flap skin appears directly proportional to degree of ischemia as long as some perfusion exists.

Michael J. Im et al (1982) in another experimental study assessed skin flap metabolism by measuring the rate of oxygen consumption and lactate

production [29]. Author had found a progressively decreasing gradient of glucose and an increasing gradient of lactate from pedicle towards the distal end. The distribution pattern of glucose and lactate is correlated with gradual impairment of microcirculation and thus the gradient of tissue glucose and lactate contents as an index of microcirculation in skin flaps.

Heden and Sollevi (1989) [30] showed that tissue hypoxia caused lactate values to increase and blood glucose values to decrease at the same time during ischemia.

W.J. Issing and C Naumann (1996) compared measurement of skin pH. Temperature, as well as fluorescence photography and computer aided digital morphometry in predicting skin flap viability [31]. Ninety male Sprague-Dawley rats were divided into three groups in which pedicles were clamped for 10, 15 and 20 hours. A standardized bipedicled skin flap was prepared, maintained by the epigastric artery, vein and nerve and sutured back in place immediately after clamping. They found that postoperative prediction of flap survival based solely upon external appearance was impossible until the 2nd postoperative day. Changes in pH were not statistically significant in the prediction of vital or necrotic flaps. The method which gave the most exact prediction about viability was fluorescein staining of flaps via tail vein.

Rojmark J et al (1998) has followed the metabolism of myocutaneous flaps using microdialysis [32]. After subcutaneous implantation of a microdialysis catheter into the flap tissue, serial samples were collected and extracellular and extracellular fluid assessed. Glucose, glycerol, and lactate concentrations were measured in the flaps and compared with those in adipose control tissue located over the hip. During the initial 15 minutes of operation glucose concentration was low. After 30 minutes there were significant rise in glucose concentration. The glycerol concentration also increased significantly, and remained increased for approximately 12 hours after the operation. The lactate concentration changed in the same direction, but stayed elevated in the flap tissue

during the entire investigation (24 Hours). Neither of these parameters changed to the same extent in the control tissue. In one of the patients a hematoma developed postoperatively in the flap. This incident was accompanied by a sharp decline in glucose, and marked additional increases in glycerol and lactate concentrations, It may well be that this "metabolic pattern" in flap tissue signals threatening flap ischemia.

Setala et al (2006) [33] reported that blood glucose values decreased 2 to 8 hours before clinical findings emerged and lactate values increased 1 to 12 hours before the findings of congestion. They speculated that the tissue was in a transient anaerobic metabolic state until the post-reperfusion flap tissue adapted to the new perfusion pattern. Unlike lactate values, after the blood glucose values increased to higher than the upper limit for temporary decreases, they remained higher than the reference value.

Jyranki J et al (2006) used microdialysis as a sampling technique to monitor the flap metabolism [7]. They had included 25 consecutive patients in the study, who underwent oral cavity reconstruction with free flaps. A microdialysis catheter was placed unto the subcutaneous adipose tissue of flap in the end of surgical procedure dialysate samples were taken on an hourly basis for 72 hours and routine clinical monitoring was carried out Later on clinical findings were compared with microdialysis sample values. Out of 25 flaps 2 flaps failed inspite came 1 to 2 hour earlier than clinical charges. Author found that during flap ischemia, the lactate/pyruvate ratio increases, glucose concentrations reduced. Whereas lactate level increased when compared with normal values.

A study done by Milan et al (2012) included 16 patients with free flaps, Of the 16 patients, (5 (31.3%) had complications of venous thrombosis in the first 24 hours [34]. This study showed that there is a decrease in capillary glycemia flaps with venous thrombosis; however because of the limited number patients with complications, it was not possible to determine a flap glycemia value that was indicative of venous thrombosis. Moreover, it was

not possible to determine whether measurement of capillary glycemia before clinical diagnosis of thrombosis would identify the flaps that would present a complication. They had concluded that the measurement of free flap capillary glycemia was not superior to clinical evaluation by an experienced professional for the detection of venous thrombosis.

A study done by R. Karwaka et al (2018) a total of 31 patients (36 flaps) underwent free tissue transfer of finger replantation with postoperative blood glucose measurement [(35)]. There were 16 male patients and 15 female patients. There were no diabetic patients or the patients receiving insulin. Blood glucose measurement were done at 0, 1, 24, 48 hours. Out of 36 flaps, 27 flaps showed no signs of congestion postoperatively and completely survived, 3 flaps demonstrated sings of congestion but improved without re-exploration, 4 flaps demonstrated signs of congestion but improved after the re-exploration, and 2 flaps demonstrated signs of congestion and eventually became necrotic despite the re-exploration. They measured ratio of blood glucose level change (RBGCs) measurement for monitoring. The RBCGs at the points in time when the venous thrombosis was detected were compared with those at the points in time when the flap demonstrated no venous thrombosis. Of the 36 flaps, 30 flaps demonstrated no venous thrombosis and 6 flaps demonstrated venous thrombosis. Four flaps demonstrated signs of congestion but improved after the re-exploration. The mean RBCGs at the point in time when the venous thrombosis was detected was -7.61mg/dl and those at times when the flap demonstrated no venous thrombosis was 0.10mg/dl, the former being significantly lower than the later is. Study showed that flap monitoring method using RBCGs measurement, can salvage some flaps from the congestion due to venous thrombosis without unnecessary re-exploration.

Thus, the aim of present experimental study was to compare the clinical assessment and intracapillary lactate measurements during monitoring of free flaps. Therefore in the present study, we propose the use capillary

measurement of lactate for free flaps monitoring. This method of assessment of flap viability is simple, cost effective and requires little special equipment.

MATERIALS AND METHODS

SOURCE OF DATA:

A prospective study was conducted on 30 consecutive patients admitted in operated Department of Plastic surgery, Dayanand Medical College and Hospital, Ludhiana who fulfill the inclusion criteria and none of the exclusion criteria. The protocol was submitted to and approved by the Institutional Ethical Committee.

METHOD OF COLLECTION OF DATA

Inclusion criteria:

Study was conducted on all the consenting patients who underwent any type of flap surgery.

Exclusion criteria:

Patients under 10 years of age and pregnant patients.

Flaps that do not bleed on pinprick are excluded from the study

All diabetic patients and patients who are critically ill are excluded from the study.

Included patients were informed about the study with a written document, and their signed informed consent was collected. Patients were allowed to withdraw from the study at any time. The surgical procedure was then performed. At the end of the procedure, the skin paddle was left accessible for the Flap Prick assay and clinical monitoring. First postoperative examination of the flap was immediately done after the end of the surgical procedure. Skin paddle color and temperature, skin capillary refill time, and bleeding characteristics with a pin prick observed. Measurements for capillary lactate were made with device, (Lactate-ProTM,). The blood drop required was obtained with disposable diabetes lancing device or a 25G needle. Blood lactate measurement will be done at 0, 3, 6, 12, 24 and 48 hrs after surgery. Along with blood lactate measurements clinical evaluation of the flap was done at same 0, 3, 6, 12, 24, and 48 hrs. Blood lactate measurement was also done when ever flap show any signs of deterioration in viability in between these intervals.

STATISTICAL ANALYSIS:

Data was expressed in terms of frequency distribution (number of cases) and relative frequencies (percentages) as appropriate and mean ± standard deviation (± SD). Chi square analysis was performed to check the level of significance. p-value < 0.005 was considered significant. Receiver operating curve analysis was done to assess the specificity and sensitivity of lactate in free flaps. All statistical calculations were done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

Picture 1: Lactometer with strips.

Picture 2: Capilary blood lactate measurement from distal margin of flap

OBSERVATIONS AND RESULTS

Over a period of 19 months (February 2020 to August 2021), 30 patients were included in the study with a minimum age of 11 years and maximum age of 73 years. Table-1 shows the frequency distribution of total cases (n=30) according to age with total 9 cases below 40 years, 8 cases between 41 to 50 years, 5 cases between 51-60 years and 8 cases above 60 years of age. Out of total 30 cases, there were 5 women (16.7%) and 25 men (83.3%) as shown below in table-2.

Table 1: Frequency distribution of total cases (n=30) according to Age range.

Age	No. of cases	Percentage
< 40	9	30.0%
41-50	8	26.7%
51-60	5	16.7%
> 60	8	26.7%
Total	30	100.0%

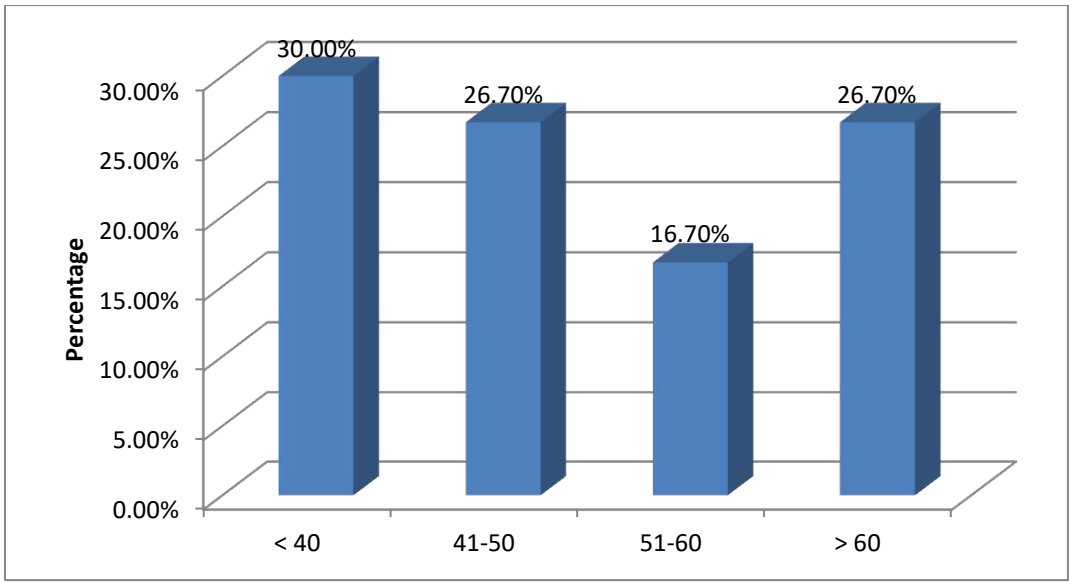

Figure 1: Frequency distribution of total cases (n=30) according to Age range.

Table 2: Frequency distribution of total cases (n=30) according to Gender.

SEX(M/F)	No. of cases	Percentage
F	5	16.7%
M	25	83.3%
Total	30	100.0%

According to Table 3, frequency distribution of Mode of onset of symptoms in cases, Indicating trauma in 8 cases , cancer in 18 cases (15 head and neck, 1 limb soft tissues) , 2 sacral pressure sore , 1 electric burn , one diabetic foot.

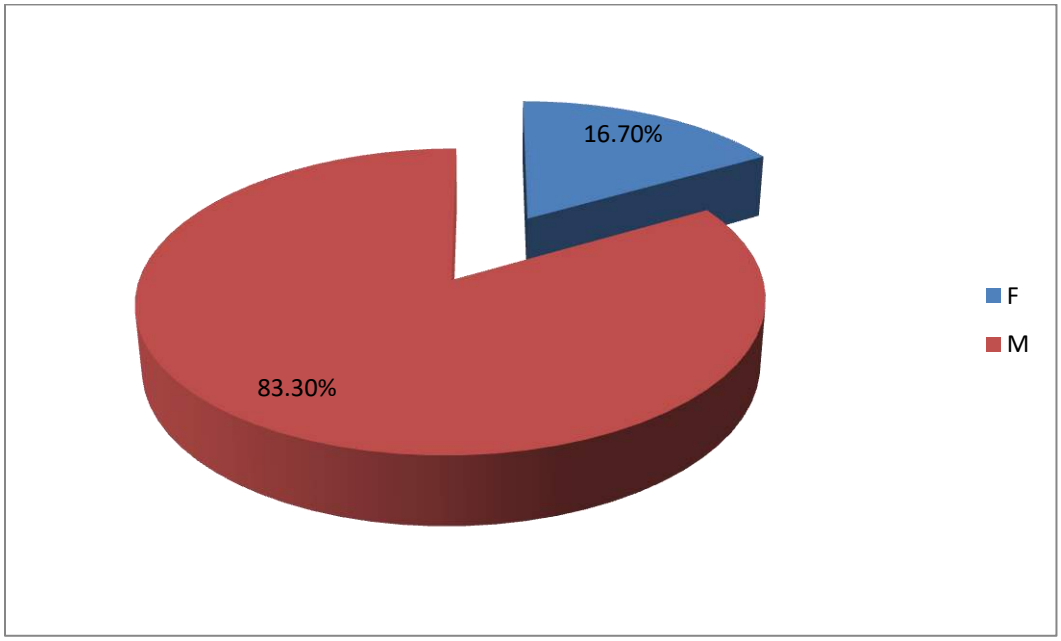

Figure 2: Frequency distribution of total cases (n=30) according to Gender.

Table 3: Frequency distribution of total cases (n=30) according to wound site.

WOUND SITE	No. of cases	Percentage
Intra Oral Cancer	18	60 %
Post Electric burn hand	1	3.3%
Post traumatic wound leg /foot	4	13.34%
Sacral pressure sore	1	3.3%
SCC of foot	1	3.3%
Post Trauma /amputation wound to upper limb	4	13.34%
Gluteal pressure ulcer	1	3.3%
Total	30	100.0%

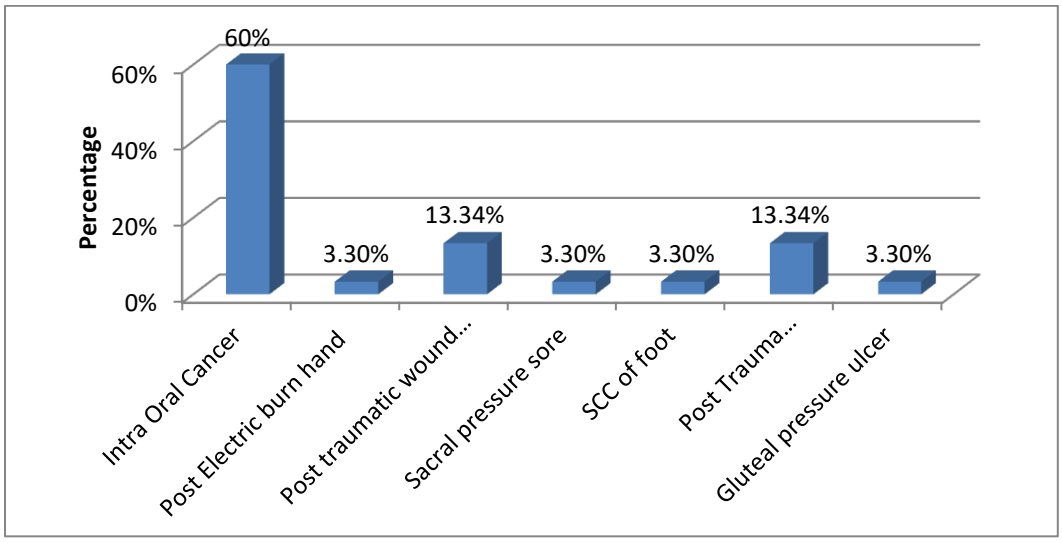

Figure 3: Frequency distribution of total cases (n=30) according to wound site.

Table 4: Frequency distribution of type of flaps used in study cases (n=30).

TYPE OF FLAP	No. of cases	Percentage
Cross leg flap	2	6.7%
Free ALT flap	5	16.7%
Free fibular flap	4	13.3%
FREE LD Flap	1	3.3%
FREE RADIAL ARETERY FLAP	5	16.7%
Gluteal flap	2	6.7%
Groin flap	4	13.3%
LD pedicled flap	2	6.7%
PMMC flap	4	13.3%
Reverse sural artery flap	1	3.3%
Total	30	100.0%

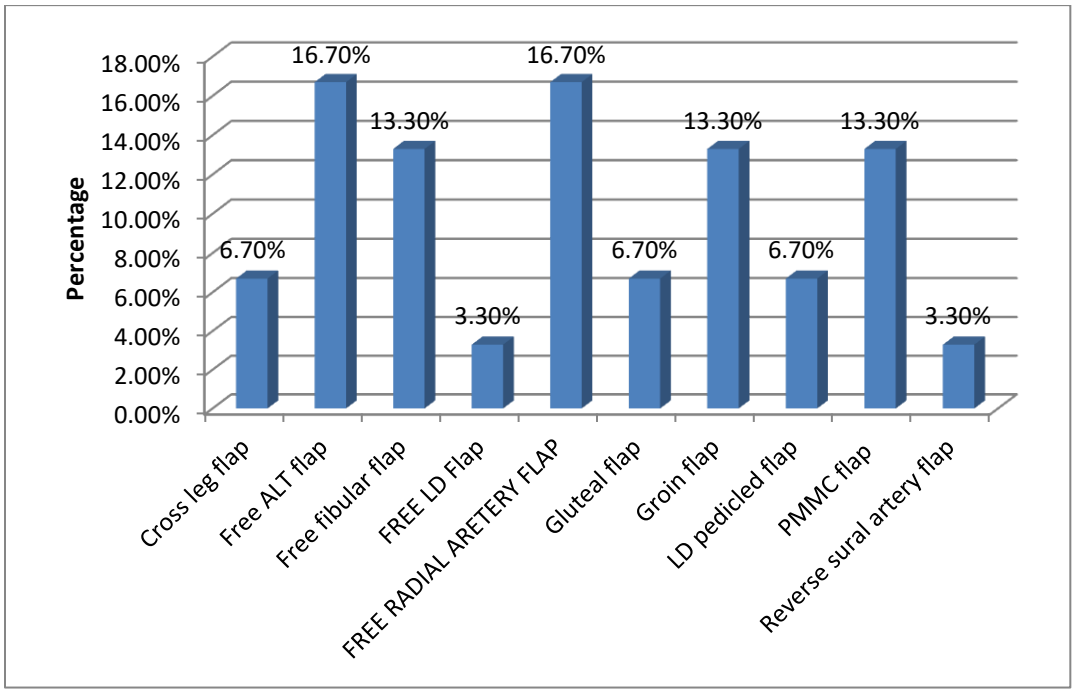

Figure 4: Frequency distribution of type of flaps used in study cases (n=30).

Table 5a: Frequency distribution of type of flaps used in study cases (n=30).

TYPE OF FLAP	No. of cases	Percentage
PEDICLED FLAP	15	50.0%
FREE FLAP	15	50.0%

Table-4 shows the types of flaps used in the study which includes: 5 Freeradial forearm flap, 5 Free anteriolateral tight flap [ALT]), 4 Free osteocutaneous fibular flaps, 1 Free latissimus dorsi, 2 pedicled latissimus dorsi, 4 Pectoris Major myocutaneous flap, 2 Cross leg flap, 2 Gluteal flap, 4 Groin flap and 1 Reverse sural artery flap.

Moreover, In present study 15 pedicled (50%) and 15 (50%) free flaps were taken as shown in table-5. For each free flap patient, the reconstruction needed one arterial anastomosis, and one or two venous anastomoses. No vascular bridge was needed.

Furthermore, Table 5a and Table 5b indicate the frequency distribution of type of free flaps and type of pedicled flap in individual subgroups respectively having 15 cases.

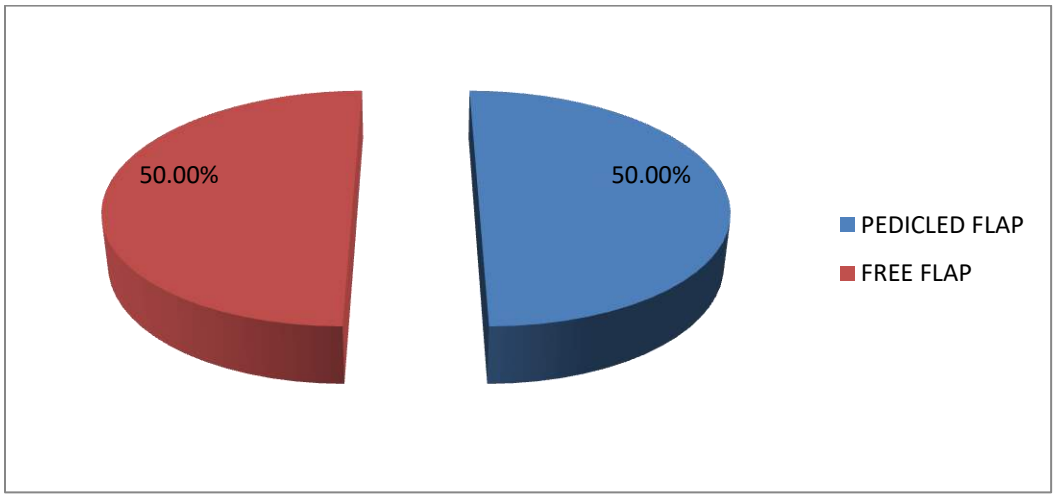

Figure 5a: Frequency distribution of type of flaps used in study cases (n=30).

Table 5b: Frequency distribution of type of free flaps used in study cases (n=15).

TYPE OF FREE FLAP	No. of cases	Percentage
ALT flap	5	33.3%
Fibular flap	4	26.7%
LD Flap	1	6.7%
RADIAL ARETERY FLAP	5	33.3%

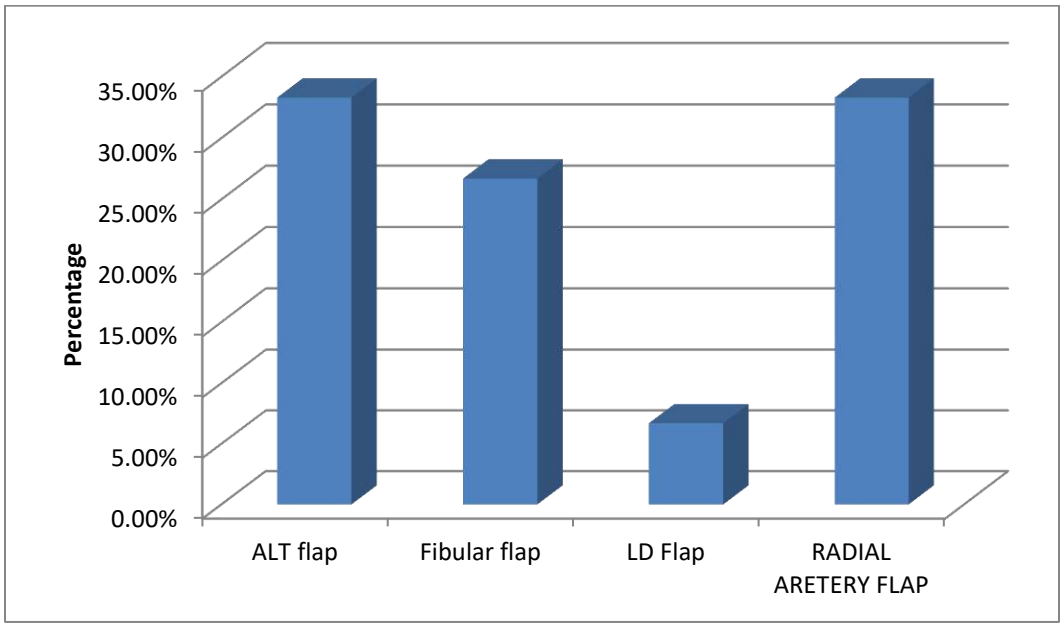

Figure 5b: Frequency distribution of type of free flaps used in study cases (n=15).

Table 5c: Frequency distribution of type of Pedicled flaps used in study cases (n=15).

TYPE OF PEDICLED FLAP	No. of cases	Percentage
Cross leg flap	2	13.3%
Gluteal flap	2	13.3%
Groin flap	4	26.7%
LD pedicled flap	2	13.3%
PMMC flap	4	26.7%
Reverse sural artery flap	1	6.7%

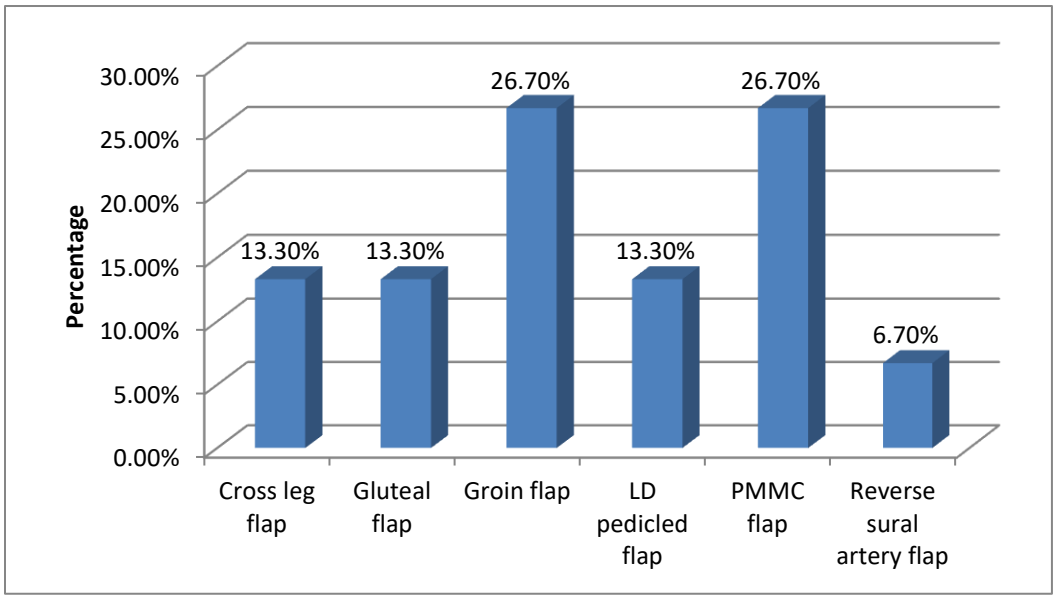

Figure 5c: Frequency distribution of type of Pedicled flaps used in study cases (n=15).

Table 6: Frequency distribution of flaps with distal ischemia in total study cases (n=30).

TYPE OF FLAP	Distal Ischemia	
	No. of cases	Percentage
Cross leg flap	1	12.5%
Free ALT flap	2	25.0%
FREE LD Flap	1	12.5%
Gluteal flap	2	25.0%
PMMC Flap	1	12.5%
Reverse sural artery flap	1	12.5%
Total	8	100.0%

Table-6 shown above indicates the total number of distally ischemic flaps and their frequency distribution according to the type of flap used in the present study. Patients with no flap complications include 22 patients (73.34%).

Clinical evaluation of the flap includes post-op flap examination in terms of its color change, capillary refill, bleeding characteristic and its temperature with evolution of time. Table 7a and 7b shown below suggests the frequency distribution of total study cases (n=30) on the basis of post-operative clinical examination outcome of flaps and shows 100 % survival rate of all the flaps at 0 hr and 1 hr respectively. Clinical examination implies significant normal clinical findings in flaps of all the cases after 0 hr as per the frequency distribution that reduces after 1 hr without altering the survival outcome of the flaps.

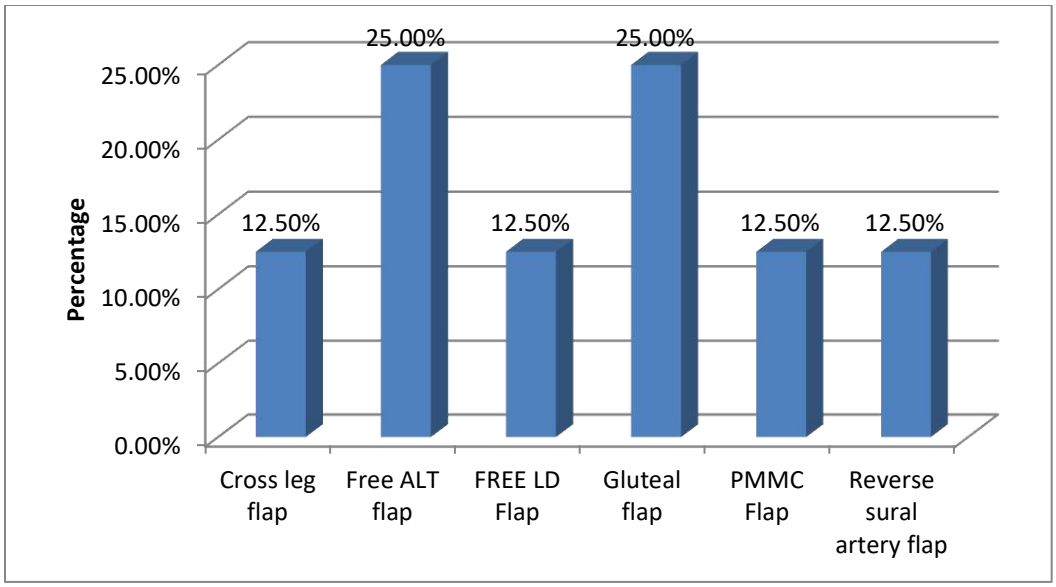

Figure 6: Frequency distribution of flaps with distal ischemia in total study cases (n=30).

Table 7a: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 0 hrs according to clinical examination.

CLINICAL FINDINGS AT 0 HRS		OUTCOME OF FLAP AT 0 HRS		Total
		Survived		
		No. of cases	Percentage	
COLOUR	SAS	30	100.0%	30
	Changed	0	0.0%	0
CAPILLARY REFILL	Normally Delayed	30	100.0%	30
	Delayed	0	0.0%	0
	Immediate	0	0.0%	0
	Absent	0	0.0%	0
BLEEDING CHARACTERISTICS	Arterial	29	96.7%	29
	No bleed	0	0.0%	0
	Venous	1	3.3%	1
TEMPERATURE	Warm	30	100.0%	30
	Cold	0	0.0%	0
Total		30	100.0%	30

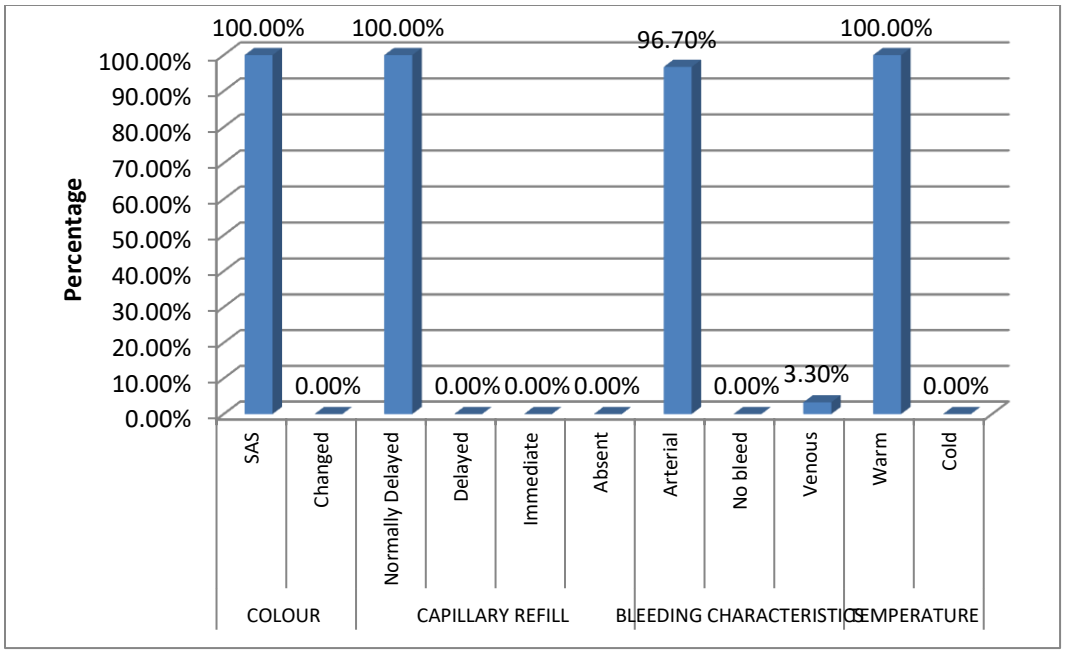

Figure 7a: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 0 hrs according to clinical examination.

Table 7b: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 1 hrs according to clinical examination.

CLINICAL FINDINGS AT 1 HRS		OUTCOME OF FLAP AT 1 HRS		Total
		Survived		
		No. of cases	Percentage	
COLOUR	SAS	29	96.7%	29
	Changed	1	3.3%	1
CAPILLARY REFILL	Normally Delayed	30	100.0%	30
	Delayed	0	0.0%	0
	Immediate	0	0.0%	0
	Absent	0	0.0%	0
BLEEDING CHARACTERISTICS	Arterial	25	83.3%	25
	No bleed	0	0.0%	0
	Venous	5	16.7%	5
TEMPERATURE	Warm	28	93.3%	28
	Cold	2	6.7%	2
Total		30	100.0%	30

Likewise, table 7c, 7d, 7e and 7f suggests the frequency distribution of total study cases (n=30) on the basis of post-operative clinical examination outcome of flap with different time durations. At 6 hrs, outcome shows 02 distally ischaemic and 28 survived flaps. At 12 hrs, outcome shows 06 distally ischaemic and 24 survived flaps. At 24 hrs, outcome shows 07 distally ischaemic and 23 survived flaps whereas outcome at 48 hrs shows 08 distally ischaemic flaps and 22 survived flaps. Analysis of the association of survival of flap on the basis of clinical examination was

done by Chi-square analysis and results implicated highly significant association of the role of clinical evaluation in the outcome of flap at p value <0.005.

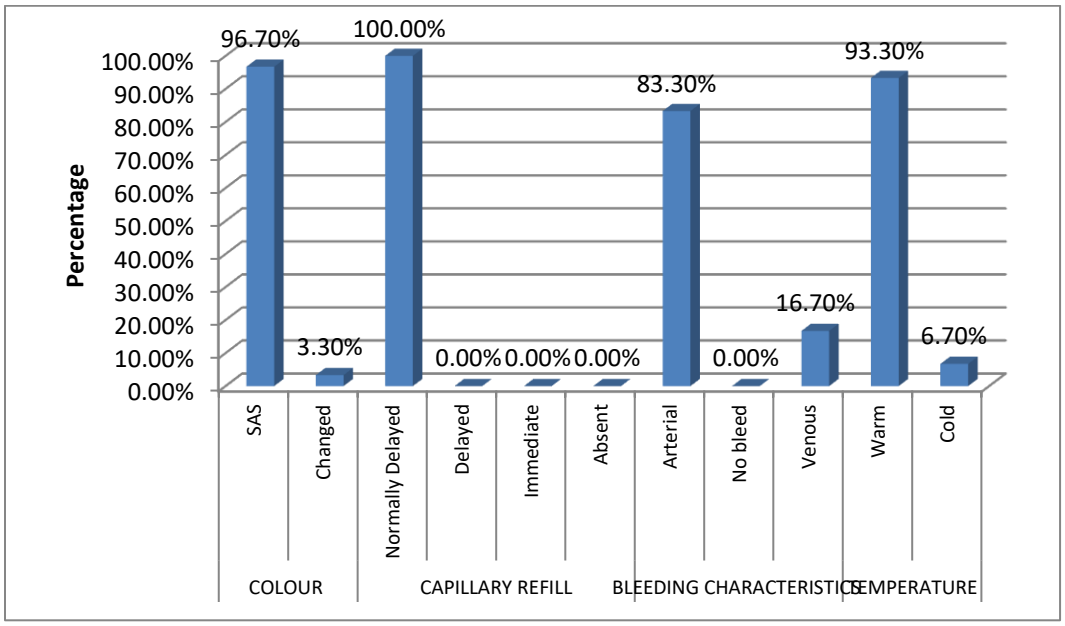

Figure 7b: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 1 hrs according to clinical examination.

Table 7c: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 6 hrs according to clinical examination at distal margin of flaps.

CLINICAL FINDINGS AT 6 HRS		OUTCOME OF FLAP AT 6 HRS				Total	Chi-square value	p-value
		Distally Ischemic		Survived				
COLOUR	SAS	1	50.0%	4	14.3%	5	8.357	0.034
	Changed	1	50.0%	24	85.7%	25		
CAPILLARY REFILL	Normally Delayed	1	50.0%	24	85.7%	25	14.571	0.001
	Delayed	0	0.0%	4	14.3%	4		
	Immediate	0	0.0%	0	0.0%	0		
	Absent	1	50.0%	0	0.0%	1		
BLEEDING CHARACTERISTICS	Arterial	0	0.0%	18	64.3%	18	30.00	0.0001
	No Bleed	2	100.0%	0	0.0%	2		
	Venous	0	0.0%	10	35.7%	10		
TEMPERATURE	Warm	0	0.0%	22	78.6%	22	5.893	0.064
	Cold	2	100.0%	6	21.4%	8		
Total		2	100.0%	28	100.0%	30		

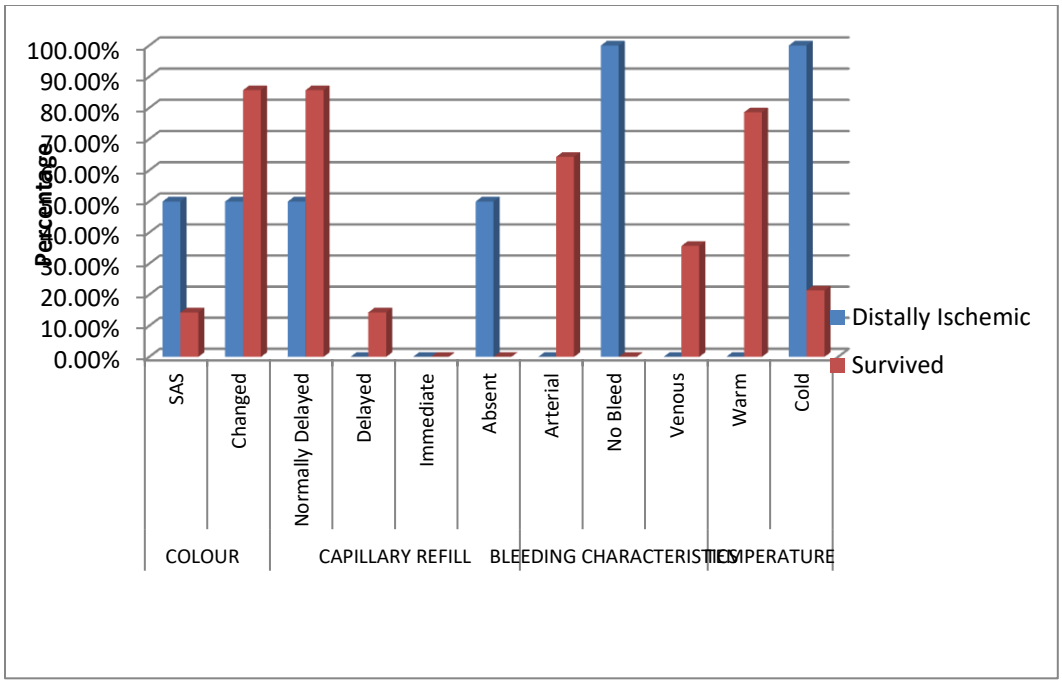

Figure 7c: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 6 hrs according to clinical examination at distal margin of flaps.

Table 7d: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 12 hrs according to clinical examination at distal margin of flaps.

CLINICAL FINDINGS AT 12 HRS		OUTCOME OF FLAP AT 12 HRS				Total	Chi-square value	p-value
		Distally Ischemic		Survived				
COLOUR	SAS	0	0.0%	20	83.3%	20	15.000	0.001
	Changed	6	100.0%	4	16.7%	10		
CAPILLARY REFILL	Normally Delayed	2	33.3%	23	95.8%	25	15.375	0.001
	Delayed	1	16.7%	1	4.2%	2		
	Immediate	0	0.0%	0	0.0%	0		
	Absent	3	50.0%	0	0.0%	3		
BLEEDING CHARACTERISTICS	Arterial	0	0.0%	19	79.2%	19	21.07	0.0001
	No Bleed	4	66.7%	0	0.0%	4		
	Venous	2	33.3%	5	20.8%	7		
TEMPERATURE	Warm	0	0.0%	22	91.7%	22	20.625	0.0001
	Cold	6	100.0%	2	8.3%	8		
Total		6	100.0%	24	100.0%	30		

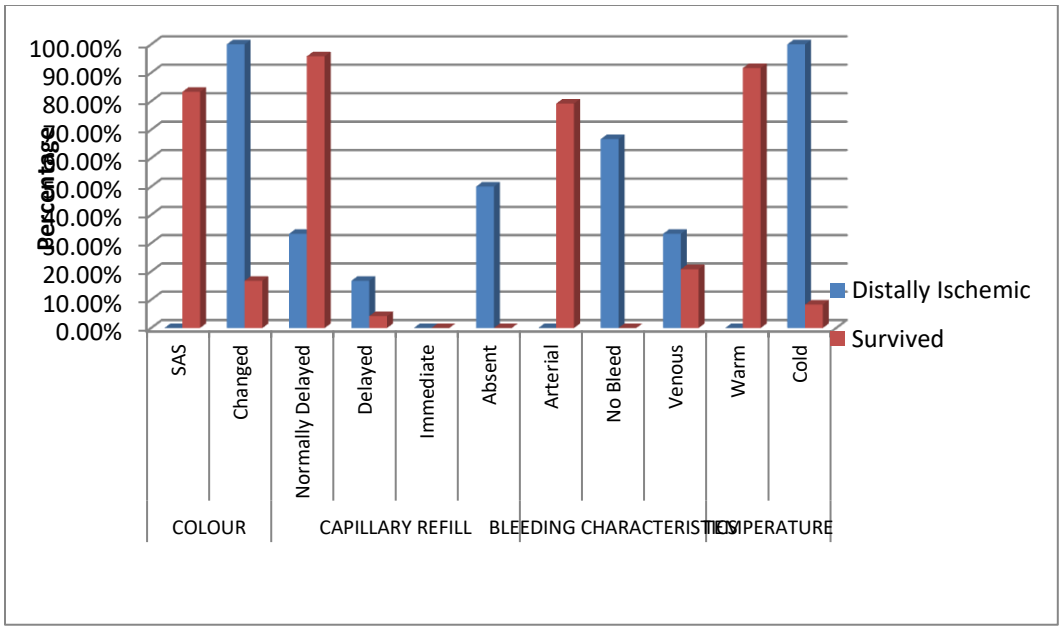

Figure 7d: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 12 hrs according to clinical examination at distal margin of flaps.

Table 7e: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 24 hrs according to clinical examination at distal margin of flaps.

CLINICAL FINDINGS AT 24 HRS		OUTCOME OF FLAP AT 24 HRS				Total	Chi-square value	p-value
		Distally Ischemic		Survived				
COLOUR	SAS	0	0.0%	20	87.0%	20	18.261	0.001
	Changed	7	100.0%	3	13.0%	10		
CAPILLARY REFILL	Normally Delayed	1	14.3%	22	95.7%	23	24.653	0.001
	Delayed	0	0.0%	1	4.3%	1		
	Immediate	0	0.0%	0	0.0%	0		
	Absent	6	85.7%	0	0.0%	6		
BLEEDING CHARACTERISTICS	Arterial	0	0.0%	20	87.0%	20	21.48	0.0001
	No Bleed	6	85.7%	1	4.3%	7		
	Venous	1	14.3%	2	8.7%	3		
TEMPERATURE	Warm	0	0.0%	20	87.0%	20	18.261	0.0001
	Cold	7	100.0%	3	13.0%	10		
Total		7	100.0%	23	100.0%	30		

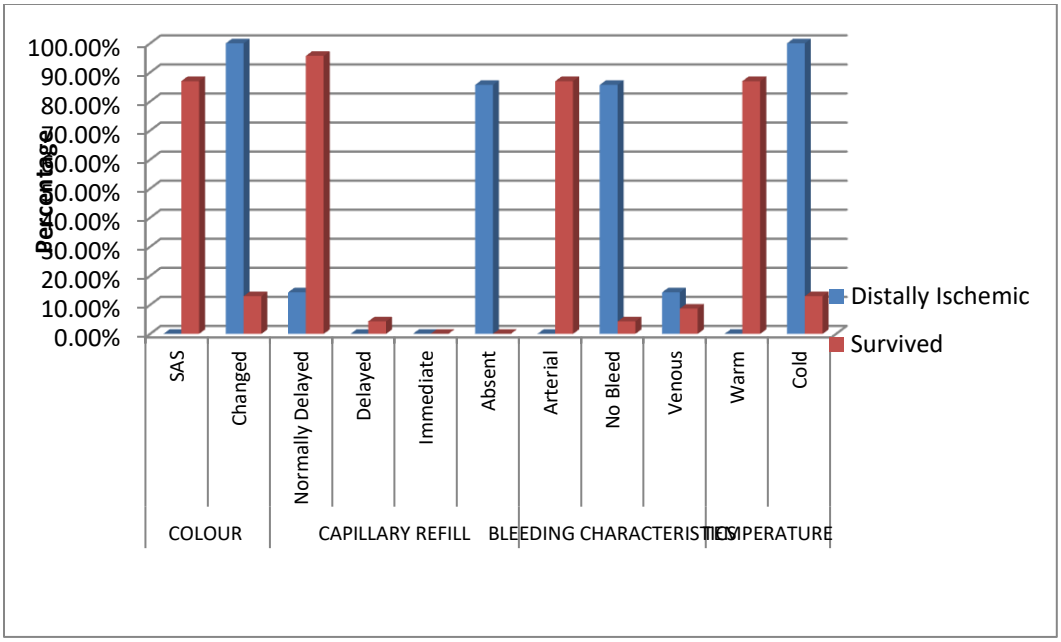

Figure 7e: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 24 hrs according to clinical examination at distal margin of flaps.

Table 7f: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 48 hrs according to clinical examination at distal margin of flaps.

CLINICAL FINDINGS AT 48 HRS		OUTCOME OF FLAP AT 48 HRS				Total	Chi-square value	p-value
		Distally Ischemic		Survived				
COLOUR	SAS	0	00.0%	22	100.0%	22	25.109	0.001
	Changed	8	87.5%	0	0.0%	8		
CAPILLARY REFILL	Normally Delayed	0	00.0%	00	0.0%	0	20.625	0.001
	Delayed	2	25.0%	22	100.0%	24		
	Immediate	0	0.0%	0	0.0%	0		
	Absent	6	75.0%	0	0.0%	6		
BLEEDING CHARACTERISTICS	Arterial	0	0.0%	22	100.0%	22	30.00	0.0001
	No Bleed	8	100.0%	0	0.0%	8		
	Venous	0	0.0%	0	0.0%	0		
TEMPERATURE	Warm	0	0.0%	22	100.0%	22	30.00	0.0001
	Cold	8	100.0%	0	0.0%	8		
Total		8	100.0%	22	100.0%	30		

Table 8a and 8b shows the level of lactate measurement at 0hr and 1 hr of outcome of flap. All the flaps survived at 0hr and 1 hr without any variation in an average value of lactate i.e. 6.13± 2.30.

Table 8c, 8d, 8e and 8f shows the comparative analysis of levels of lactate at 6 hrs, 12 hrs, 24 hrs and 48 hrs of flap survival. Variation within the groups were observed by applying ANOVA suggestive of highly significant correlation ($p<0.005$) initially at 0 hrs in various outcomes of flap survival. But non-significant correlation was found at 1 hr and 6 hr levels of measured lactate at 6 hr, 12 hr and 24 hr of flap survival. On the contrary highly significant correlations ($p<0.005$) were observed with time evolution in flaps survived upto 48 hrs.

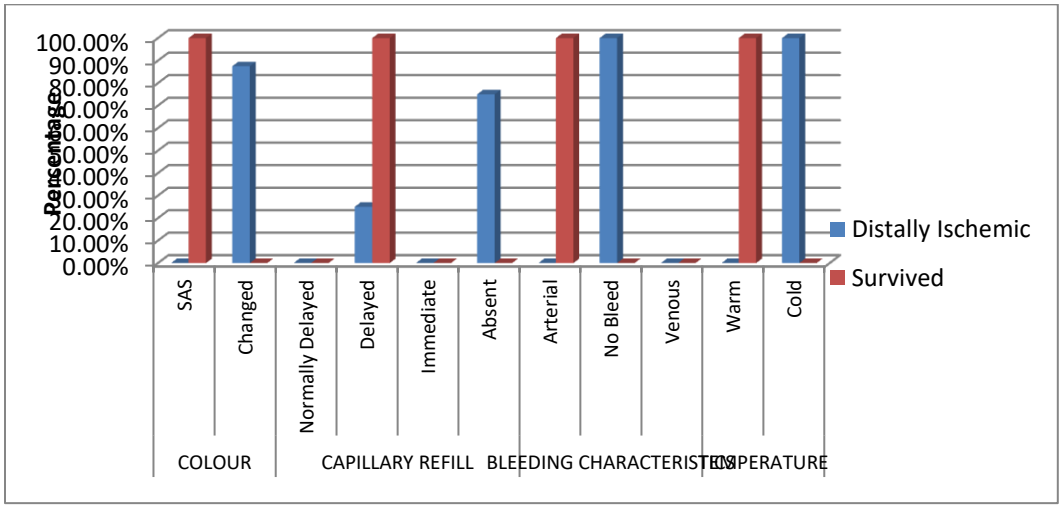

Figure 7f: Frequency distribution of total study cases (n=30) on the basis of post-operative outcome of flaps at 48 hrs according to clinical examination at distal margin of flaps.

Table 8a: Values of Lactate measurement in survived/Ischemic flaps at 0 hrs.

At 0 hours	Survived (n=30)		Distally Ischemic flaps (n=00)
LACTATE	Mean	SD	
At 0 hours	2.63	1.235	
At 1 hours	5.15	2.238	
At 6 hours	7.12	3.473	
At 12 hours	8.51	4.000	
At 24 hours	7.00	3.250	
At 48 hours	5.63	3.311	
Average	6.13	2.30	

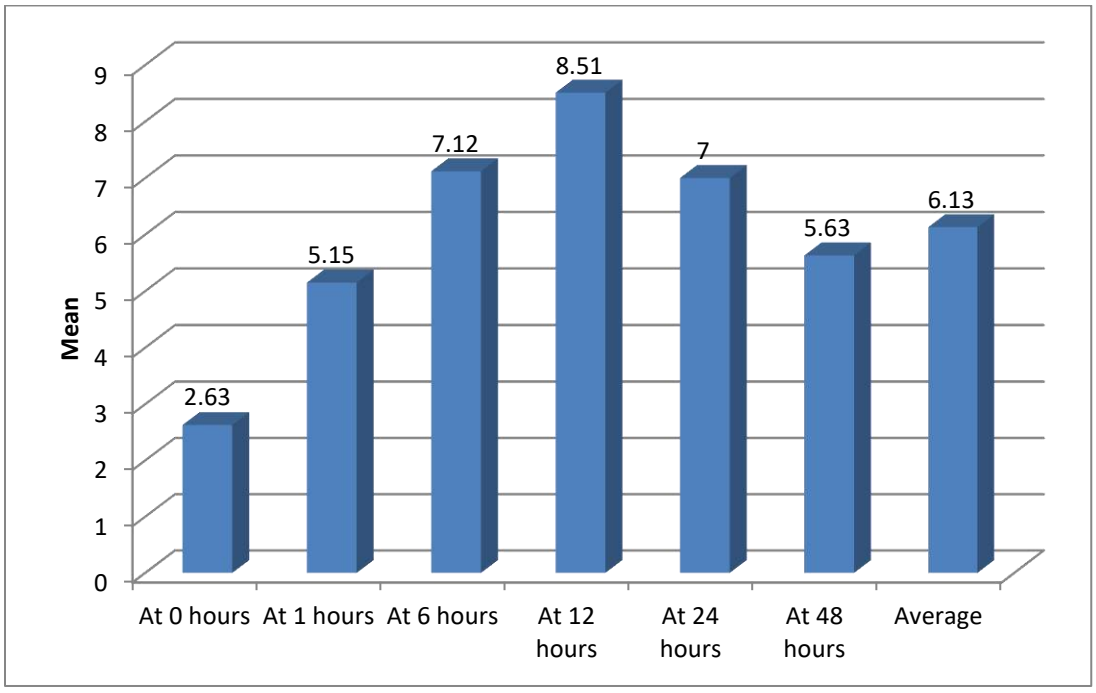

Figure 8a: Values of Lactate measurement in survived/Ischemic flaps at 0 hrs.

Table 8b: Values of Lactate measurement in survived/Ischemic flaps at 1 hrs.

At 1 hours	Survived (n=30)		Distally ischemic flaps (n=00)
LACTATE	Mean	SD	
At 0 hours	2.63	1.235	
At 1 hours	5.15	2.238	
At 6 hours	7.12	3.473	
At 12 hours	8.51	4.000	
At 24 hours	7.00	3.250	
At 48 hours	5.63	3.311	
Average	6.13	2.30	

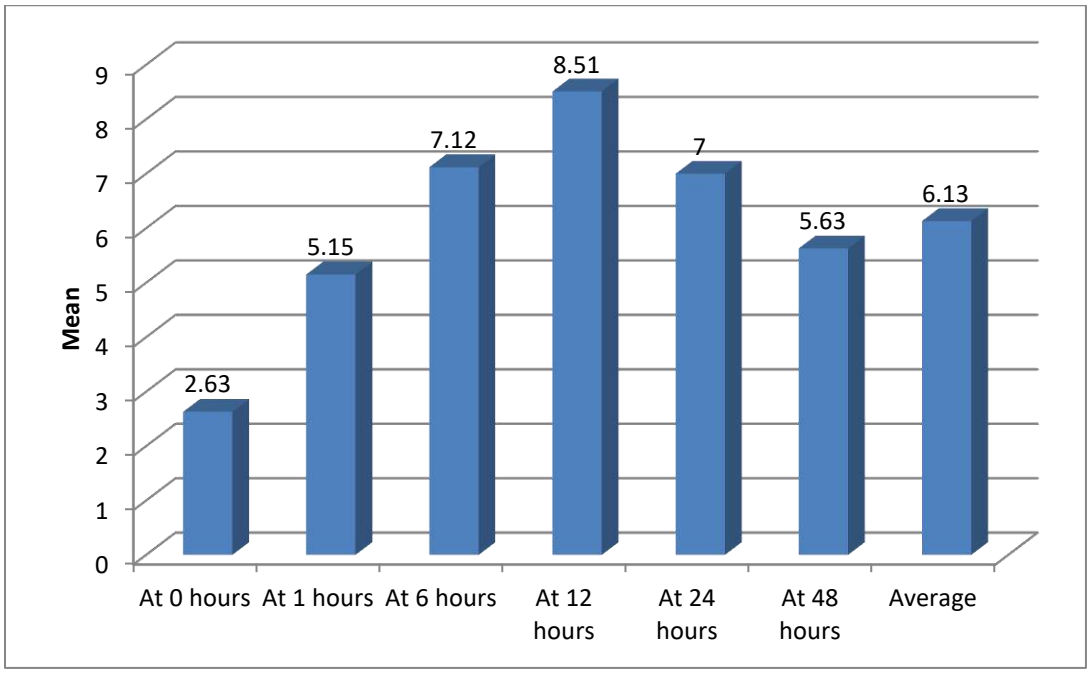

Figure 8b: Values of Lactate measurement in survived/Ischemic flaps at 1 hrs.

Table 8c: Values of Lactate measurement in survived / distally ischaemic flaps at 6 hrs.

At 6 hours	Survived (n=28)		Distally Ischemic(n=2)		Z	p-value
LACTATE	Mean	SD	Mean	SD		
At 0 hours	2.50	1.17	4.40	0.57	-2.238	0.033
At 1 hours	4.97	2.17	7.65	2.19	-1.689	0.102
At 6 hours	6.63	3.03	14.00	0.00	-3.381	0.002
At 12 hours	8.51	4.00				
At 24 hours	7.00	3.25				
At 48 hours	5.63	3.31				

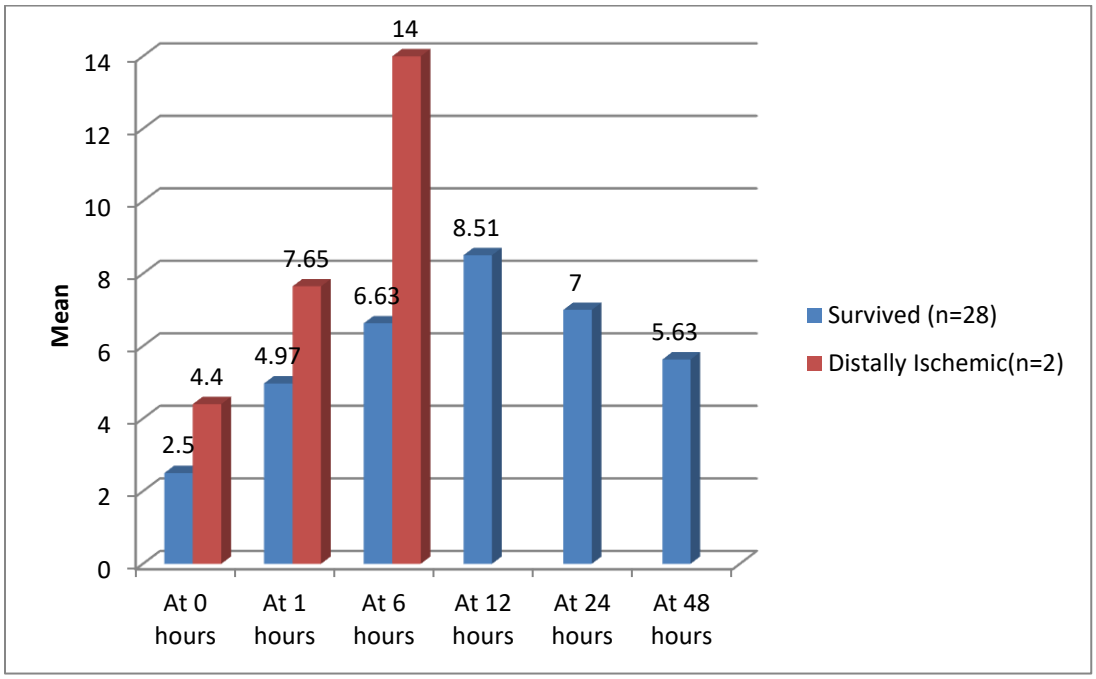

Figure 8c: Values of Lactate measurement in survived / distally ischaemic flaps at 6 hrs.

Table 8d: Values of Lactate measurement in survived / distally ischaemic flaps at 12 hrs.

At 12 hours	Survived (n=24)		Distally Ischemic(n=6)		Z	p-value
LACTATE	Mean	SD	Mean	SD		
At 0 hours	2.30	0.88	3.93	1.66	-3.365	0.002
At 1 hours	4.84	2.17	6.37	2.26	-1.527	0.138
At 6 hours	6.49	3.13	9.63	3.92	-2.094	0.045
At 12 hours	7.55	3.45	14.25	1.26	-3.794	0.001
At 24 hours	7.00	3.25				
At 48 hours	5.63	3.31				

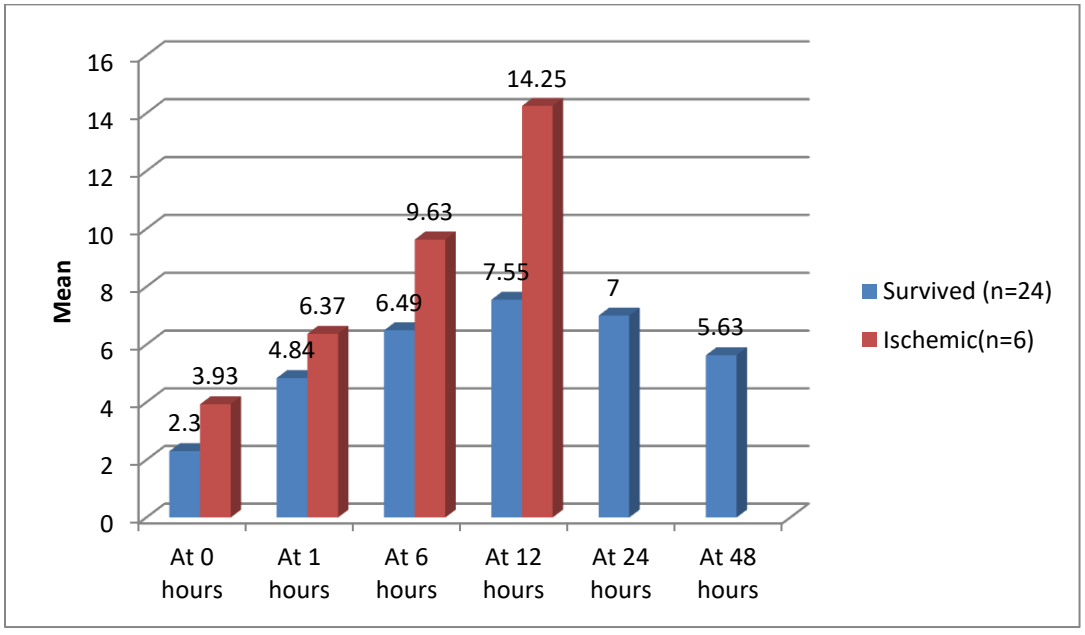

Figure 8d: Values of Lactate measurement in survived / distally ischaemic flaps at 12 hrs.

Table 8e: Values of Lactate measurement in survived / distally ischaemic flaps at 24 hrs.

At 24 hours	Survived (n=23)		Distally Ischemic(n=7)		Z	p-value
LACTATE	Mean	SD	Mean	SD		
At 0 hours	2.32	0.89	3.66	1.68	-2.792	0.009
At 1 hours	4.91	2.19	5.91	2.38	-1.038	0.308
At 6 hours	6.51	3.20	9.11	3.84	-1.801	0.082
At 12 hours	7.48	3.51	13.22	2.55	-3.442	0.002
At 24 hours	6.70	2.95	14.00	.	-2.420	0.024
At 48 hours	5.63	3.31	.	.		

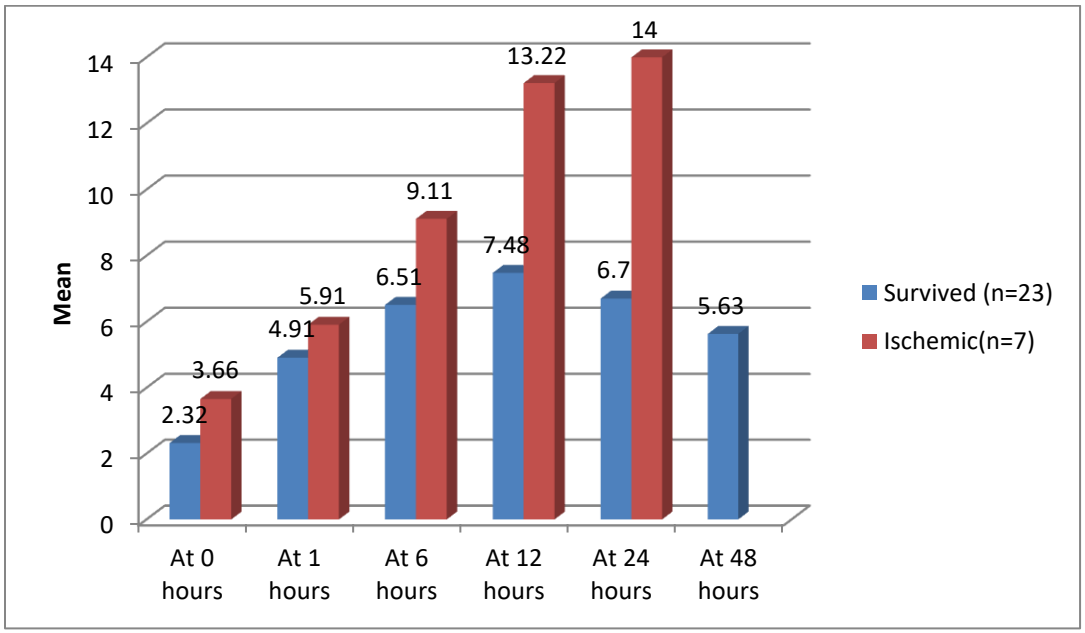

Figure 8e: Values of Lactate measurement in survived / distally ischaemic flaps at 24 hrs.

Table 8f: Values of Lactate measurement in survived / distally ischaemic flaps at 48 hrs.

At 48 hours	Survived (n=22)		Distally Ischemic(n=8)		Z	p-value
LACTATE	Mean	SD	Mean	SD		
At 0 hours	2.20	0.69	3.83	1.63	-3.901	0.001
At 1 hours	4.77	2.14	6.18	2.33	-1.554	0.131
At 6 hours	6.17	2.82	9.73	3.95	-2.742	0.011
At 12 hours	7.14	3.18	13.52	2.39	-4.554	0.000
At 24 hours	6.41	2.68	13.50	0.71	-3.664	0.001
At 48 hours	5.20	2.67		.		

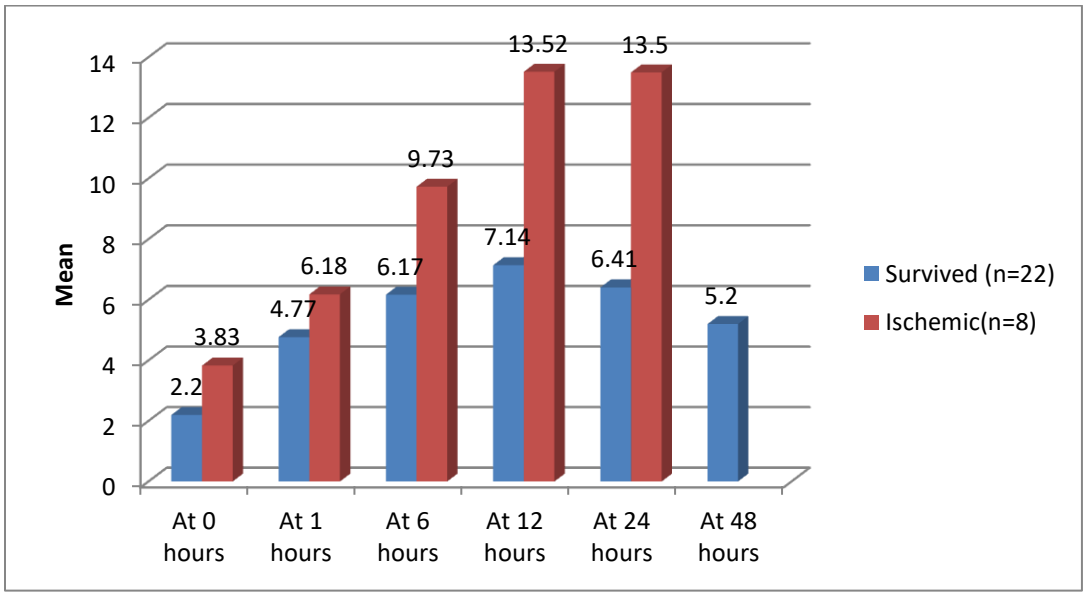

Figure 8f: Values of Lactate measurement in survived / distally ischaemic flaps at 48 hrs.

Table 9: Values of Lactate measurement in survived/distally ischaemic flaps.

FINAL OUTCOME OF FLAP	Survived (n=22)		Distally Ischemic(n=8)		Z	p-value
LACTATE	Mean	SD	Mean	SD		
At 0 hours	2.20	0.69	3.83	1.63	-3.901	0.001
At 1 hours	4.77	2.14	6.18	2.33	-1.554	0.131
At 6 hours	6.17	2.82	9.73	3.95	-2.742	0.011
At 12 hours	7.14	3.18	13.52	2.39	-4.554	0.000
At 24 hours	6.41	2.68	13.50	0.71	-3.664	0.001
At 48 hours	5.20	2.67		.		
Average	5.32	1.91	8.38	1.81	-3.941	0.000

Table 9 shown above suggests the comparison of variance within cases group by using ANOVA on the basis of survival of flap with evolution of time. The average values of Lactate in the survived and distally ischaemic flap outcome are 5.32 ±1.91 and 8.38 ±1.81 respectively. Highly significant correlation was observed within the groups with $p<0.005$.

Using these thresholds the characteristics of the test assessed by ROC analysis shown below would be: sensitivity = 100 % and specificity = 68.2%. No technical mistakes during measurements, nor abnormal environment of the flap was noticed. This measurement was made upto 48 hours after the clinical diagnosis and unsuccessful surgical revision.

Moreover, for the venous or areterial thrombosis/ compression hematoma the lactate values exceeded the threshold before the clinical diagnosis. The threshold was exceeded by 2.0 hours before the clinical diagnosis.

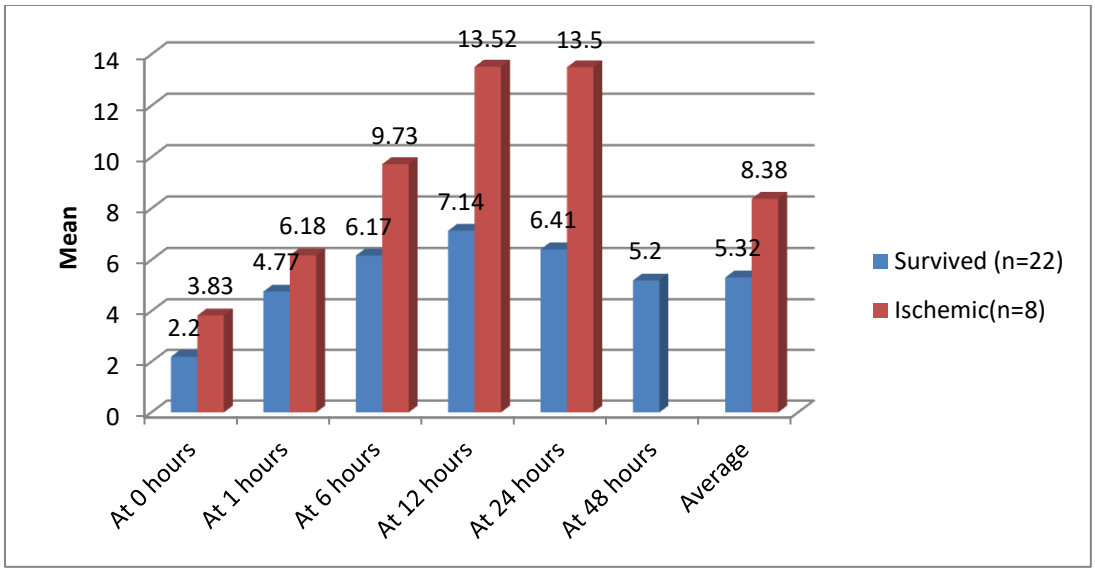

Figure 9: Values of Lactate measurement in survived/distally ischaemic flaps.

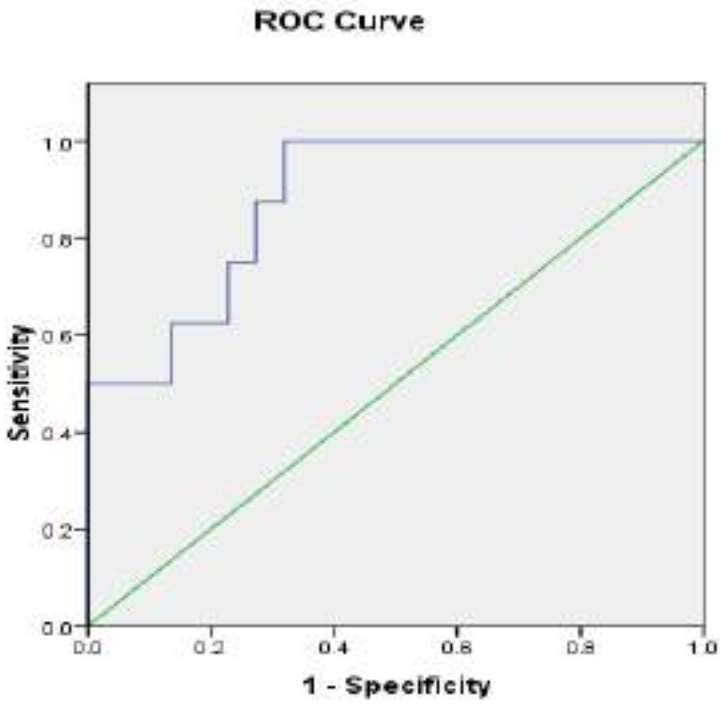

Figure 10: ROC curve of lactate values in predicting flap survival and distal ischemia of flap

Test Result Variable(s):average lactate

Area	Std. Error[a]	p-value	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.881	.063	.002	.751	1.000

Coordinates of the Curve

Test Result Variable(s):average lactate

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity	Specificity	Youden Index
.75	1.000	1.000	0.000	0.000
2.47	1.000	.955	0.045	0.045
3.22	1.000	.909	0.091	0.091
3.36	1.000	.864	0.136	0.136
3.56	1.000	.818	0.182	0.182
3.73	1.000	.773	0.227	0.227
3.93	1.000	.727	0.273	0.273
4.08	1.000	.682	0.318	0.318
4.33	1.000	.636	0.364	0.364
4.58	1.000	.591	0.409	0.409
4.64	1.000	.545	0.455	0.455
4.97	1.000	.500	0.500	0.500
5.49	1.000	.455	0.545	0.545
5.77	1.000	.409	0.591	0.591
5.88	1.000	.364	0.636	0.636
6.09	1.000	.318	0.682	0.682

6.31	.875	.318	0.682	0.557
6.56	.875	.273	0.727	0.602
6.73	.750	.273	0.727	0.477
6.81	.750	.227	0.773	0.523
7.07	.625	.227	0.773	0.398
7.31	.625	.182	0.818	0.443
7.68	.625	.136	0.864	0.489
8.05	.500	.136	0.864	0.364
8.28	.500	.091	0.909	0.409
8.63	.500	.045	0.955	0.455
8.87	.500	.000	1.000	0.500
9.11	.375	.000	1.000	0.375
9.29	.250	.000	1.000	0.250
10.50	.125	.000	1.000	0.125
12.67	.000	.000	1.000	0.000

Table 10: Mean Values of lactate measurement in both survived and distally ischaemic flaps.

		Outcome		Total
		Distally Ischemic	Survived	
lactate	< 6.09	0	15	15
	> 6.09	8	7	15
Total		8	22	30

Thus the present study suggests that the values of lactate measured were found to be below 6.09 mmol/l in 15 out of 22 survived flaps whereas values above 6.09 mmol/l in all the 08 distally ischemic flaps as shown above in table 10. This suggests a significant association of the measurement of lactate levels at cut-off value of 6.09 mmol/L with the survival of flap.

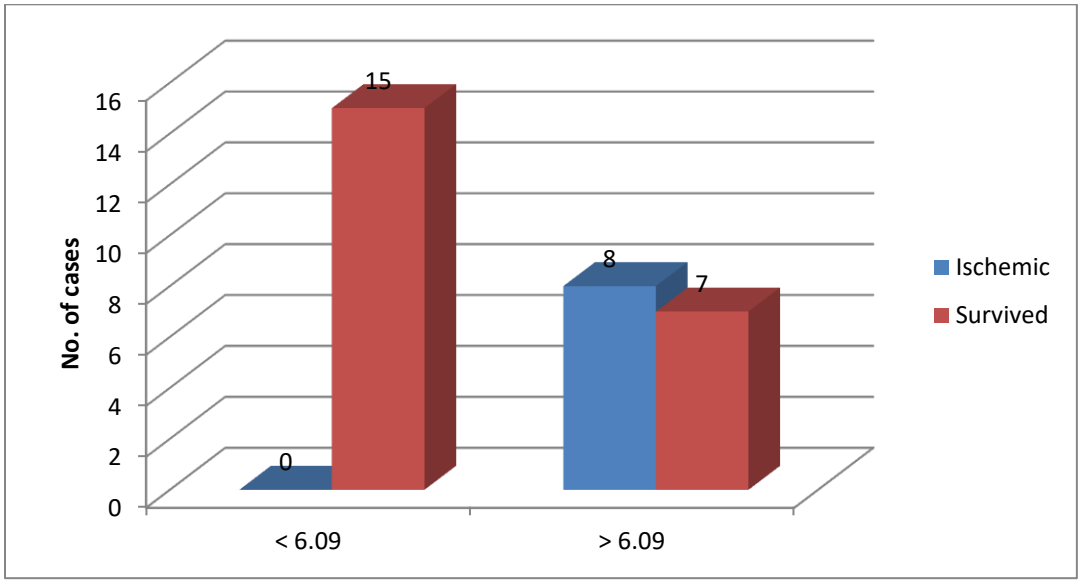

Figure 11: Mean Values of lactate measurement in both survived and distally ischaemic flaps.

DISCUSSION

The purpose of flap monitoring is to detect perfusion failure and establish the need for a timely surgical intervention before irreversible tissue damage appears. It is reported that the salvage rate of flaps is inversely related to the time interval between the onset of pedicle impairments and their clinical recognition. Monitoring of free flaps is therefore of major importance and clinical monitoring remains the most used technique because of lack of low-cost and non-invasive techniques [(14)]. The present study suggested an efficient, simple and cheap technique to detect early thrombotic events in monitoring flaps.

In this prospective study, measurements of capillary lactate in the flaps were done and compared to standardized clinical monitoring during the first 48hrs. Two sets of data (eventful versus uneventful postoperative period) were analyzed to define the thresholds of lactate for diagnosis of pedicle complications, and to establish parameters for this screening test.

Present study was performed over a period of 19 months (February 2020 to August 2021) and 30 patients were included in the study with a minimum age of 11 years and maximum age of 73 years with 5 women (16.7%) and 25 men (83.3%) as shown in table-2.

Physical examination remains the cornerstone of flap monitoring and are considered by most surgeons to be the gold standard technique .In our study Clinical evaluation of the flap includes post-op flap examination in terms of its color change, capillary refill, bleeding characteristic and its temperature with evolution of time and initially 100 % survival rate of all the flaps were observed at 0 hr and 1 hr shown in table 7a and 7b.

Likewise, table 7c, 7d, 7e and 7f suggests the frequency distribution of total study cases (n=30) on the basis of post-operative clinical examination outcome of flap with different time durations. At 6 hrs, outcome shows 02 distally ischaemic and 28 survived flaps. At 12 hrs, outcome shows 06 distally ischaemic and 24 survived flaps. At 24 hrs,

outcome shows 07 distally ischaemic and 23 survived flaps whereas outcome at 48 hrs shows 08 distally ischaemic flaps and 22 survived flaps. Analysis of the association of survival of flap on the basis of clinical examination was done by Chi-square analysis and results implicated highly significant association of the role of clinical evaluation in the outcome of flap at p value <0.005.

Thus, in patients, changes in the appearance of the flap suggestive of a microvascular complication lagged 60 minutes after the adjunctive monitoring methods indicated that a problem had occurred. Therefore clinical examination remains the most frequently used, least reproducible and little to no objective technique [9]. Clinical assessment depends on evaluator experience and it is only reliable when the flap color changes significantly into pale or blueish [36].

Table 8a and 8b shows the level of lactate measurement at 0hr and 1 hr of outcome of flap. All the flaps survived at 0hr and 1 hr without any variation in an average value of lactate i.e. 6.13± 2.30.

Table 8c, 8d, 8e and 8f shows the comparative analysis of levels of lactate at 6 hrs, 12 hrs, 24 hrs and 48 hrs of flap survival. Variation within the groups were observed by applying ANOVA suggestive of highly significant correlation ($p<0.005$) initially at 0 hrs in various outcomes of flap survival. But non-significant correlation was found at 1 hr and 6 hr levels of measured lactate at 6 hr, 12 hr and 24 hr of flap survival. On the contrary highly significant correlations ($p<0.005$) were observed with time evolution in flaps survived upto 48 hrs.

Table 9 shown above suggests the comparison of variance within cases group by using ANOVA on the basis of survival of flap with evolution of time. The average values of Lactate in the survived and distally ischaemic flap outcome are 5.32 ±1.91 and 8.38 ±1.81 respectively. Highly significant correlation was observed within the groups with $p<0.005$.

Using these thresholds the characteristics of the test assessed by ROC analysis shown below would be: sensitivity = 100 % and specificity =

68.2%. No technical mistakes during measurements, nor abnormal environment of the flap was noticed. This measurement was made upto 48 hours.

Present study suggests that the values of lactate measured were found to be below 6.09 mmol/l in 15 out of 22 survived flaps whereas values above 6.09 mmol/l in all the 08 distally ischemic flaps as shown above in table 10. This suggests a significant association of the measurement of lactate levels at cut-off value of 6.09 mmol/L with the survival of flap.

Moreover Capillary measurement of lactate is definitely a low-cost technique. Consumables for Six strips of monitoring cost less then Rs2000 The use of the Lactate-ProTM device is similar to capillary glucose measurement devices.

Two of the ischemic flaps, Free ALT flap, were reexplored at 12 hr and 24 hr at lactate value of 15 mmol/l and 14 mmol/l and survived

One of the ischemic flap, free LD flap, reexplored at 6hr at lactate value 14 and flap not survived and lost

Two of ischemic flaps, pedicled gluteal flap got distal necrosis, advancement of flap margin was done at 12 hr and 24 hr at lactate value from distal of flap of 13 mmol/l and 14 mmol/l

One of ischemic flap, PMMC flap, distal marginal necrosis occurred at 12hrs at lactate value of 14 mmol/l

One of the ischemic flap, Cross leg flap, necrosed superficially at distal margin at 12 hrs at lactate value of 14 , necrotic margins are excised and skin grafting was done

One of the ischemic flap, Reverse sural artery flap , distal 3cm of flap necrosed, at 6 hrs, necrosed part of flap excised , flap advancement with grafting was done

Our study was supported by the study conducted by Henault B. et al, 2014 **(14)**. According to their study application of lactate test in study

population reveals that all diagnosis of the pedicle thromboses and the compressive hematoma are several hours before clinical diagnosis. Nevertheless, if threshold had been used during the monitoring, three patients (false positives) would have undergone surgical revision in the absence of pedicle impairment.

This screening test is much more accurate than glucose monitoring, like in Hara et al. study [37], which has sensitivity of 88% and specificity of 82%.

Henault B. et al, 2014 [14] also found that the false positive measured at the exit of operating room was probably due to the short delay (3 hours) after revascularization or inset , which was too short to allow lactate to normalise [38].

In order to minimize the false positive rate due to early measurements, we simply should not take into account the first measurements for a positive diagnosis of pedicle impairment, and should wait for the second measurement to be clear. Indeed, an expected value for first measurement is not easily definable, because of important variability of period between revascularization and first measurement, and tissue dependent kinetics of lactate [33, 38].

No technical mistakes during measurements, nor abnormal environment of the flaps was found to explain the other false positive values above the threshold, for verification to not lose the benefit of early diagnosis, and correct a possible false positive.

Bruising of the skin paddle due to the pricks is the only complication linked to the technique. However, bruises always resolved by themselves, with no scarring. Systamic lactemia are low in physiological conditions: normal superior value is usually around 2.0 mmol/L.

Unlike values obtained with microdialysis, the values measured with our technique did not allow us to differentiate between arterial and venous occlusion [17, 21]. However, this differentiation is not essential,

because surgical revision of pedicle impairments will routinely explore and check both the artery and the vein.

Setala et al [33] reported transitions similar to the temporary postoperative decrease in blood glucose values and increase in lactate values. The researchers speculated that the tissue was in a transient anaerobic metabolic state until the post-reperfusion flap tissue adapted to the new perfusion pattern. Unlike lactate values, after the blood glucose values increased to higher than the upper limit for temporary decreases, they remained higher than the reference value.

Jyränki et al [7] also reported that the blood glucose value increased over time. The cause was not clear, but a report indicated that the intra-flap blood glucose value temporarily decreased when insulin was administered, suggesting that generally, it is easily influenced by the blood glucose value of the body. Based on this, the intra flap blood glucose was possibly driven up by an increase in the blood glucose value of the body, which was caused by a postoperative stress reaction or transfusion, as the intra-flap circulation stabilized. This revealed that blood glucose value transitions are unstable, even in flaps without impeded blood flow.

Several reports described the effects of blood flow obstruction on blood glucose and lactate values. Heden and Sollevi [30] demonstrated that tissue hypoxia caused lactate values to increase and blood glucose values to decrease at the same time during ischemia. Furthermore, in this study, a statistically significant decrease in glucose value and an increase in lactate value were observed from ischemia to reperfusion. This suggested that even portable measuring instruments can detect blood flow disturbance in flaps.

Setala et al [33] reported that blood glucose values decreased 2–8 h before clinical findings emerged, and lactate values increased 1–12 h before the findings of congestion. However, this study did not clarify which value first reacted to the congestion. By contrast, unmetabolized lactate accumulation,5 pressure increase within capillaries, and arterial blood flow

rate of decrease during congestion have been speculated to cause a supply shortage of blood glucose.17 Accordingly, we can surmise that the lactate value increases first, followed later by the decrease in blood glucose value.

In addition, only the lactate value demonstrated a significant difference in the logistic interpretive analysis. These results show that lactate values respond more significantly than blood glucose values during congestion. Several studies on cutoff lactate values in flaps with impeded blood flow have been published [7, 14, 39]. On the basis of the animal testing performed by Setala et al.,18 intra-flap lactate values of >9.3 mmol/L (sensitivity, 93%; specificity, 91%) indicated impeded blood flow.

Meanwhile, Jyränki et al. [7] reported in a clinical study that the lactate values in flaps without impeded blood flow were <7 mmol/L, whereas Henault et al.4 used >6.4 mmol/L (sensitivity, 100%; specificity, 96.9%) as the cutoff value. In an experimental case, the optimum cutoff values for sensitivity and specificity were calculated to be >4.2 and 6.7 mmol/L, respectively.

Kindermann et al [40] reported that the speed at which lactate was produced exceeded the speed at which it was metabolized when the blood lactate value exceeded 4.0 mmol/L, causing it to accumulate. In addition, Henning et al. [41] reported that the blood lactate values of patients with life-threatening ischemia were >4.0 mmol/L.

Bakker et al. [42] reported that the blood lactate values of patients with life-threatening multiorgan failure were >6.6 mmol/L. Our cutoff blood lactate value was close to the critical value reported by Henning et al [41] and Bakker et al., [42] which was an effective indicator of whether a patient would survive or not. Therefore, in the future, we may need to reassess our method of correcting the values we obtained using lactate measuring instruments.

In 1998, Röjdmark et al [32] measured intra-flap blood glucose and lactate values to evaluate flap blood flow. In addition, Sorensen et al [22]

also used those values for free jejunum flaps. Most previous studies [22, 33, 39] that measured blood glucose and lactate values inside the flap tissue used microdialysis. Microdialysis is a method used during surgery where a catheter is embedded in the flap tissue (e.g., skin, muscle, or fat) to measure the target substance. This allows for continuous measurement and excellent objectivity, but the complicated procedure and need for professional management have been cited as having disadvantages [14].

By contrast, a study by Sakakibara et al [15] examined blood glucose values in free flaps with a simple measuring instrument. In 2013, another study examined the usefulness of measuring lactate by using the same method [14]. The major advantage of the simple measuring instrument is its ability to measure quickly and easily. However, one of the drawbacks of simple measuring instruments is that they can only evaluate flaps exposed on the body surface, whereas microdialysis can evaluate buried flaps. A previous study showed that diabetes mellitus increased the risk of postoperative complications by 1.76 OR and resulted in a flap failure rate of 2.05% in patients with head and neck free flap reconstruction [43].

However, a simple measuring instrument can be used to obtain objective information quickly and easily in cases where an inexperienced observer is unsure of whether blood flow is impeded based on clinical findings. In such instances, the cutoff values reported in past studies [33, 37] and in the present study can be a good reference. Indeed, previous studies showed good accuracy of handheld lactate measuring devices in monitoring lactate levels in critically injured/ill patients [44, 45]. Moving forward, we must attempt to determine whether blood flow is impeded by referencing measured values rather than clinical findings and then performing salvage surgery. Accumulating data when the blood flow is impeded is essential in accomplishing this task.

We are cognizant that metabolic abnormalities can arise in patients with cancer, causing lactic acid impairment in solid tumors, and that

hepatic dysfunction is common in patients with chronic alcoholism. Furthermore, diabetic treatment may impair the lactic acid macro environment. However, for this study we did not obtain patient data to assess these issues. We used a simple measuring instrument to determine the intra-flap blood lactate values from the time of flap vein obstruction to 48 h after operation in 30 cases of reconstruction.

Therefore, our results suggest that lactate values responded sensitively during congestion. Lactate measurement with lactometer is easily and can quickly evaluate flap ischemia. Objective information can be easily added to subjective clinical findings by using portable measuring instruments like lactometer when evaluating flap ischemia.

Nursing staff can do easily and repeatedly measure flap lactate with Lactometer and disposable strips

Staff can inform lactate values to surgeon, which when raised above threshhold, surgeon can come and evaluate clinically

Moreover, lactate measure is more reliable in intraoral flap monitoring as clinical evaluation in depth might be difficult and can easily be misunderstood

At the same time study of more cases is urgently needed to increase the reliability of the cutoff value.

SUMMARY AND CONCLUSION

A prospective study of role of flap blood lactate measurement in monitoring of flaps was done in the department of plastic surgery at Dayanand Medical College and Hospital Ludhiana from February 2020 to August 2021. This study included 30 patients who had undergone any type of flap surgery. All the diabetic and the critically ill patients were excluded from the study and flaps that did not bleed on pinprick were also excluded from the study.

Flap capillary blood lactate measurement was done at 0,1,6,12,24 and 48hrs. Blood lactate measurement was done from distal margin of the flap. Along with blood lactate measurement clinical evaluation of the flap was also done at the same interval of time. Out of the 30 flaps, there was distal ischemia of the 8 flaps and 22 flaps were healthy. In the clinical evaluation of flap color, capillary refill, temperature and bleeding characteristics were measured.

On the basis of this study we concluded that blood lactate level of flaps increases significantly in case of congestion or ischemia of flaps and correlate well with the clinical changes of flap.

Rise in blood lactate level can be used as an early indicator of flap ischemia and provide opportunity to salvage flaps but serial and continuous monitoring of flap blood lactate levels is required. By ROC curve analysis flap blood lactate level of 6.09 mg/dl was used as a cut off value with sensitivity and specificity of 100 % and 68.2 %respectively.

Therefore, our results suggest that capillary lactate values responded sensitively during congestion. Capillary Lactate measurement with lactometer is easily and can quickly evaluate flap ischemia. Objective information can be easily added to subjective clinical findings by using portable measuring instruments like lactometer when evaluating flap ischemia.

Nursing staff can easily use and repeatedly measure flap capillary lactate with Lactometer and disposable strips

Staff can inform lactate values to surgeon, which when raised above thresh hold, surgeon can come and evaluate flap clinically

Moreover, lactate measurement is more reliable in intraoral flap monitoring as clinical evaluation in depth might be difficult and can easily be misunderstood.

Capillary Blood lactate measurement is an easy, accessible and objective method of flap monitoring and combination of blood lactate measurement with clinical monitoring methods is likely to reduce postoperative complications of flap congestion. Being a quantitative method flap blood lactate measurement has no subjective variability as in clinical monitoring methods.

Despite the significant result, our study was limited by a small sample size and limited no. of flaps. In order to validate the use of blood Lactate for flap monitoring a study using a larger sample size with a wider array of flaps needs to be done to further endorse the use of blood lactate for flap monitoring.

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Picture 3: CASE 1: PMMC FLAP

Picture 4: CASE 2: FREE FIBULAR FLAP

Picture 5: CASE 3: RADIAL ARTERY FORARM FREE FLAP

Picture 6: CASE 4: REVERSE SURAL ARTERY FLAP

Picture 7: CASE 5: PMMC FLAP

Picture 8: CASE 6: RADIAL ARTERY FORARM FREE FLAP

Picture 9: CASE 7: GLUTEAL FLAP

Picture 10: CASE 8: REVERSE SURAL ARTERY FLAP

S.NO	MRD. NO	NAME	Age	SEX (M/F)	MODE OF ONSET(Post traumatic)Blunt/Sharp)	WOUND SITE	TYPE OF FLAP DURATION(hrs)	COLOUR 0 HRS
1	926523	KS	60	M	ca right cheek	oromandibular	pmmc	SAS
2	924780	RS	24	M	Traumatic Amputation	left hand, ulnar finger and metacarpel	groin flap	SAS
3	929402	K	24	M	Electric burn	Left hand and forearm	groin flap	SAS
4	931564	SD	50	F	Ulcerative growth right cheek	Intraoral site	free fiblar flap	SAS
5	930215	RS	65	M	Intraoral cancer excission	Intraoral site	FREE FIBULAR FLAP	SAS
6	921224	H	24	M	Saccral pressure sore	Sacral region	gluteal flap	SAS
7	524703	RRM	45	M	Ca left Cheek	Buccal Mucosa	free fiblar flap	SAS
8	69192	JS	51	M	Ca Tongue	Tongue	pmmc	SAS
9	938460	RS	65	M	Oral cancer	Buccal Mucosa	pmmc	SAS
10	941228	KS	63	M	Ca right buccal mucosa	Buccal Mucosa	free ALT flap	SAS
11	941228	KS	63	M	Ca right buccal mucosa	Buccal Mucosa	LD PEDICLED Flap	SAS
12	940276	MJ	44	F	Ca buccal mucosa	Buccal Mucosa	free fiblar flap	SAS
13	946963	KS	73	M	cancer floor of mouth	Left floor of mouth	LD PEDICLED FLAP	SAS
14	685425	JS	40	M	Trauma	right thumb	groin flap	SAS
15	686358	RK	54	M	Cancer	Intraoral site	free ALT flap	SAS
16	1003999	G	46	M	Lesion in buccal mucosa	Buccal Mucosa	free ALT flap	SAS
17	154694	AS	44	M	Lesion in buccal mucosa	Buccal Mucosa	FREE RADIAL ARETERY FLAP	SAS
18	877686	KS	50	M	Trauma to right upper limb	Right upper limb	FREE RADIAL ARETERY FLAP	SAS
19	1001008	MS	26	M	Traumatic Wound	Left ant. Leg	FREE LD Flap	SAS
20	996858	GS	40	M	Post traumatic lower leg and foot defect	Lower leg and foot	cross leg flap	SAS
21	1063461	JS	66	M	Ulcerproliferative tumour tounge	Tongue	FREE RADIAL ARETERY FLAP	SAS
22	959929	BS	11	M	Wound left foot	left foot	free ALT flap	SAS
23	942163	H	17	M	Ulcer gluteal sacral region	Gluteal Sacral region	gluteal flap	SAS
24	1024123	R	50	F	Ulcerproliferative growth buccal mucosa	Buccal Mucosa	free ALT flap	SAS
25	1011364	K	53	M	post traumatic wound	wrist	groin flap	SAS
26	1074586	SSJ	56	M	Ulcerproliferative lession buccal mucosa	Buccal Mucosa	FREE RADIAL ARETERY FLAP	SAS
27	1118239	SK	44	M	Swelling right side of face	right side of face	pmmc	SAS
28	982506	KK	66	F	Ulcerproliferative lession buccal mucosa	Buccal Mucosa	FREE RADIAL ARETERY FLAP	SAS
29	1004800	JS	65	M	Post traumatic wound left leg	Left ant. Leg	cross leg flap	SAS
30	1081705	S	32	F	SCC of foot	Left foot	Reverse sral artery flap	SAS

S.NO	MRD. NO	COLOUR 1 HRS	COLOUR 6 HRS	COLOUR 12 HRS	COLOUR 24 HRS	COLOUR 48 HRS	CAPILLARY REFILL 0 HRS	CAPILLARY REFILL 1 HRS	CAPILLARY REFILL 6 HRS	CAPILLARY REFILL 12 HRS
1	926523	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
2	924780	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
3	929402	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
4	931564	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
5	930215	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
6	921224	SAS	SAS	changed	changed	SAS	ND	ND	ND	ND
7	524703	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
8	69192	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
9	938460	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
10	941228	SAS	changed	changed	changed	changed	ND	ND	ND	ND
11	941228	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
12	940276	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
13	946963	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
14	685425	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
15	686358	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
16	1003999	changed	changed	changed	changed	changed	ND	ND	ND	A
17	154694	SAS	SAS	changed	changed	SAS	ND	ND	ND	ND
18	877686	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
19	1001008	SAS	changed	changed	changed	changed	ND	ND	D	ND
20	996858	SAS	SAS	changed	changed	changed	ND	ND	D	A
21	1063461	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
22	959929	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
23	942163	SAS	changed	changed	changed	changed	ND	ND	D	ND
24	1024123	SAS	changed	changed	changed	SAS	ND	ND	D	D
25	1011364	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
26	1074586	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
27	1118239	SAS	SAS	changed	changed	changed	ND	ND	ND	D
28	982506	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
29	1004800	SAS	SAS	SAS	SAS	SAS	ND	ND	ND	ND
30	1081705	SAS	changed	changed	changed	changed	ND	ND	A	A

S.NO	MRD. NO	CAPILLARY REFILL 24 HRS	CAPILLARY REFILL 48 HRS	BLEEDING CHARACTERISTICS AT 0 HRS	BLEEDING CHARACTERISTICS AT 1 HRS	BLEEDING CHARACTERISTICS AT 6 HRS	BLEEDING CHARACTERISTICS AT 12 HRS
1	926523	ND	ND	arterial	Venous	Venous	Venous
2	924780	ND	ND	arterial	Venous	arterial	arterial
3	929402	ND	ND	arterial	arterial	arterial	arterial
4	931564	ND	ND	arterial	arterial	arterial	arterial
5	930215	ND	ND	arterial	arterial	arterial	arterial
6	921224	ND	ND	arterial	arterial	arterial	Venous
7	524703	ND	ND	arterial	arterial	arterial	arterial
8	69192	ND	ND	arterial	arterial	arterial	arterial
9	938460	ND	ND	arterial	arterial	arterial	arterial
10	941228	ND	ND	arterial	arterial	Venous	Venous
11	941228	ND	ND	arterial	arterial	arterial	arterial
12	940276	ND	ND	arterial	arterial	arterial	arterial
13	946963	ND	ND	arterial	arterial	arterial	arterial
14	685425	ND	ND	arterial	arterial	arterial	arterial
15	686358	ND	ND	arterial	arterial	arterial	arterial
16	1003999	A	A	arterial	Venous	No Bleed	No Bleed
17	154694	ND	ND	arterial	arterial	arterial	Venous
18	877686	ND	ND	arterial	arterial	arterial	arterial
19	1001008	A	A	arterial	arterial	Venous	No Bleed
20	996858	A	A	arterial	arterial	Venous	Venous
21	1063461	ND	ND	arterial	arterial	Venous	arterial
22	959929	ND	ND	arterial	arterial	Venous	arterial
23	942163	A	A	arterial	arterial	Venous	No Bleed
24	1024123	D	ND	arterial	arterial	Venous	Venous
25	1011364	ND	ND	arterial	arterial	arterial	arterial
26	1074586	ND	ND	arterial	arterial	arterial	arterial
27	1118239	A	A	Venous	Venous	Venous	Venous
28	982506	ND	ND	arterial	arterial	Venous	arterial
29	1004800	ND	ND	arterial	arterial	arterial	arterial
30	1081705	A	-	arterial	Venous	No Bleed	No Bleed

S.NO	MRD. NO	BLEEDING CHARACTERISTICS AT 24 HRS	BLEEDING CHARACTERISTICS AT 48 HRS	TEMPERATURE AT 0 HRS	TEMPERATURE AT 1 HRS	TEMPERATURE AT 6 HRS	TEMPERATURE AT 12 HRS	TEMPERATURE AT 24 HRS
1	926523	arterial	arterial	warm	warm	warm	warm	warm
2	924780	arterial	arterial	warm	warm	warm	warm	warm
3	929402	arterial	arterial	warm	warm	warm	warm	warm
4	931564	arterial	arterial	warm	warm	warm	warm	warm
5	930215	arterial	arterial	warm	warm	warm	warm	warm
6	921224	Venous	No Bleed	warm	warm	warm	warm	Cold
7	524703	arterial	arterial	warm	warm	warm	warm	warm
8	69192	arterial	arterial	warm	warm	warm	warm	warm
9	938460	arterial	arterial	warm	warm	warm	warm	warm
10	941228	No Bleed	No Bleed	warm	warm	Cold	Cold	Cold
11	941228	arterial	arterial	warm	warm	warm	warm	warm
12	940276	arterial	arterial	warm	warm	warm	warm	warm
13	946963	arterial	arterial	warm	warm	warm	warm	warm
14	685425	arterial	arterial	warm	warm	warm	warm	warm
15	686358	arterial	arterial	warm	warm	warm	warm	warm
16	1003999	No Bleed	No Bleed	warm	Cold	Cold	Cold	Cold
17	154694	Venous	arterial	warm	warm	warm	warm	Cold
18	877686	arterial	arterial	warm	warm	warm	warm	warm
19	1001008	No Bleed	No Bleed	warm	warm	Cold	Cold	Cold
20	996858	No Bleed	No Bleed	warm	warm	Cold	Cold	Cold
21	1063461	arterial	arterial	warm	warm	warm	warm	warm
22	959929	arterial	arterial	warm	warm	warm	warm	warm
23	942163	No Bleed	No Bleed	warm	warm	Cold	Cold	Cold
24	1024123	Venous	arterial	warm	warm	warm	Cold	Cold
25	1011364	arterial	arterial	warm	warm	warm	warm	warm
26	1074586	arterial	arterial	warm	warm	warm	warm	warm
27	1118239	No Bleed	No Bleed	warm	Cold	Cold	Cold	Cold
28	982506	arterial	arterial	warm	warm	Cold	warm	warm
29	1004800	arterial	arterial	warm	warm	warm	warm	warm
30	1081705	No Bleed	No Bleed	warm	warm	Cold	Cold	Cold

S.NO	MRD. NO	TEMPERATURE AT 48 HRS	OUTCOME OF FLAP AT 0 HRS	OUTCOME OF FLAP AT 1 HRS	OUTCOME OF FLAP AT 6 HRS	OUTCOME OF FLAP AT 12 HRS	OUTCOME OF FLAP AT 24 HRS	OUTCOME OF FLAP AT 48 HRS
1	926523	warm	S	S	S	S	S	S
2	924780	warm	S	S	S	S	S	S
3	929402	warm	S	S	S	S	S	S
4	931564	warm	S	S	S	S	S	S
5	930215	warm	S	S	S	S	S	S
6	921224	Cold	S	S	S	S	DI	DI
7	524703	warm	S	S	S	S	S	S
8	69192	warm	S	S	S	S	S	S
9	938460	warm	S	S	S	S	S	S
10	941228	Cold	S	S	S	S	S	DI
11	941228	warm	S	S	S	S	S	S
12	940276	warm	S	S	S	S	S	S
13	946963	warm	S	S	S	S	S	S
14	685425	warm	S	S	S	S	S	S
15	686358	warm	S	S	S	S	S	S
16	1003999	Cold	S	S	DI	DI	DI	DI
17	154694	warm	S	S	S	S	S	S
18	877686	warm	S	S	S	S	S	S
19	1001008	Cold	S	S	S	DI	DI	DI
20	996858	Cold	S	S	S	DI	DI	DI
21	1063461	warm	S	S	S	S	S	S
22	959929	warm	S	S	S	S	S	S
23	942163	Cold	S	S	S	DI	DI	DI
24	1024123	warm	S	S	S	S	S	S
25	1011364	warm	S	S	S	S	S	S
26	1074586	warm	S	S	S	S	S	S
27	1118239	Cold	S	S	S	DI	DI	DI
28	982506	warm	S	S	S	S	S	S
29	1004800	warm	S	S	S	S	S	S
30	1081705	Cold	S	S	DI	DI	DI	DI

S.NO	MRD. NO	LACTATE AT 0	LACTATE 1	LACTATE AT 6	LACTATE AT 12	LACTATE AT 24	LACTATE AT 48	AVERAGE	FINAL OUTCOME OF FLAP
1	926523	2	6.1	11.4	11.5	3.5	6	6.75	SURVIVED
2	924780	2	10	9.5	6	4.5	12	7.33	SURVIVED
3	929402	2	1.9	3.2	4	5	3	3.18	SURVIVED
4	931564	2	7.5	10	12	11.3	8.2	8.50	SURVIVED
5	930215	4	6	9	10.1	10.2	9.1	8.07	SURVIVED
6	921224	2	3.2	6	9.1	14	-	6.86	ISCHEMIC
7	524703	3	9.2	10.2	10.1	6	5.2	7.28	SURVIVED
8	69192	2	3.1	3.6	4.2	6	3	3.65	SURVIVED
9	938460	1.8	3.5	2	2.5	5	8	3.80	SURVIVED
10	941228	5	8	14	15	13	15	11.67	ISCHEMIC
11	941228	3	4.2	5	5.2	8	6	5.23	SURVIVED
12	940276	2.8	5	7.5	8	6.2	5	5.75	SURVIVED
13	946963	2	3.2	5	7.2	7	3	4.57	SURVIVED
14	685425	1.2	3.1	4	4.2	5.1	3.2	3.47	SURVIVED
15	686358	1.2	4.2	6.2	5	4.8	3	4.07	SURVIVED
16	1003999	4.8	9.2	14	-	-	-	9.33	ISCHEMIC
17	154694	2.1	6.2	7.2	9.2	8.6	5.2	6.42	SURVIVED
18	877686	2.1	4.2	3.6	5.8	2.3	1.5	3.25	SURVIVED
19	1001008	2.6	8.2	10.2	16	-	-	9.25	ISCHEMIC
20	996858	2.6	4.2	4	14	-	-	6.20	ISCHEMIC
21	1063461	2.2	4.2	6.1	9.2	10.1	4.1	5.98	SURVIVED
22	959929	2.1	3	6.2	7.1	5.1	4	4.58	SURVIVED
23	942163	2.8	3.4	7.6	13	-	-	6.70	ISCHEMIC
24	1024123	3.2	6	9.2	14	12.1	8.1	8.77	SURVIVED
25	1011364	1.2	2	1.6	1.8	2.4	1.5	1.75	SURVIVED
26	1074586	2	3.2	4	7	5.1	3.2	4.08	SURVIVED
27	1118239	6.8	7.1	8	14	-	-	8.98	ISCHEMIC
28	982506	1.6	5.6	7.1	8.2	7.2	5	5.78	SURVIVED
29	1004800	2.8	3.6	4.2	4.8	5.6	7.2	4.70	SURVIVED
30	1081705	4	6.1	14	-	-	-	8.03	ISCHEMIC

Head of Dte DR. RAJIV K

Baba Farid University
of Health Sciences
Sadiq Road
Faridkot-151 203 (Pb). INDIA.
Phone : 01639-256232,256236
Tele/Fax : 01639-256235
Email – Examination@bfuhs.ac.in

No. BFUHS/2K21p-TH/ 11458

Date 4/11/2021

The Principal,
DMC, Ludhiana

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of **Dr** Karan Singh, a student of your college for MCh Plastic & Reconstructive Surgery along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Role of blood lactate measurement for flap monitoring

Supervisor
Dr. Rajinder Kumar Mittal
Prof. & Head,
Dept. of Plastic Surgery,
DMCH, Ludhiana.

Co-Supervisor
Dr. Sheerin Shah
Assoc. Prof.,
Dept. of Plastic Surgery,
DMCH, Ludhiana.

The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

13. If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.

ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

M.Ch

IN

PLASTIC AND RECONSTRUCTIVE SURGERY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

MARCH, 2020

DR. KARAN SINGH

DEPARTMENT OF PLASTIC AND RECONSTRUCTIVE SURGERY

DAYANAND MEDICAL COLLEGE & HOSPITAL

LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	**ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING**
For the degree of	MCh Plastic and Reconstructive Surgery
Name of the candidate	Dr. Karan Singh
Supervisor	Dr Rajinder Kumar Mittal, Professor & Head, Department of Plastic Surgery , DMCH
Co-supervisor	Dr Sheerin Shah, Associate Professor, Department of Plastic Surgery, DMCH
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Reconstruction using free flaps has become a reliable technique. Pedicle thrombosis is a dreaded complication, and the earlier diagnosis of such a complications has higher surgical salvage rate. Clinical monitoring remains the most useful but make late and unreliable diagnosis. Numerous studies aimed to find ideal monitoring techniques for free flaps. Actually the most efficient ones often deal with expensive and invasive techniques. In this study, we suggest an efficient, simple, cheap technique to detect arterial or vein thrombosis after free flaps vessels anastomosis.

Aim of Study: The aim of present study is cappillary blood lactate moitoring as predictor of flap survival.

Materials & Methods: A prospective study will be conducted on around 30 patients admitted in Department of plastic surgery, Dayanand Medical Collage and Hospital, Ludhiana who will undergo any type of flap coverage for various defects, Flaps that do not bleed on pinprick will be excluded from the study. all diabetic and critically ill pt will be excluded from the study . Blood lactate measurement will be done using the same lactometer device with a drop of blood after pin prick from free flap and for pedicled flap from distal end of the flap.

Blood lactate measurement will be done at 0, 1, 3, 6, 12, 48 hrs after surgery.

Clinical Significance: This will lead to the development of simple, rapid and easy method for flap monitoring without requiring complex appratus.

Keywords: Free flap; Arterial thrombosis; venous thrombosis; Lactate; Complication.

(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-Supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING"** exist in the Department of Plastic and Reconstructive surgery, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate herself under our supervision and guidance.

Supervisor

Dr. Rajinder Kumar Mittal
Professor & Head
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Co-Supervisor

Dr Sheerin Shah
Associate Professor
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Head of the Department

Dr. Rajinder Kumar Mittal
Professor & Head
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Place : _____

Date : _____

APPROVAL PROFORMA
BY RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr Karan Singh
Department	Plastic and Reconstructive Surgery
Topic of Thesis	Role of blood lactate measurement for flap monitoring
Likely date of appearing in PG examination	2022
Date of enrollment	27 August, 2019
Name of Head of Department	Dr. Rajinder K. Mittal
1) Supervisor **2) Co-Supervisor(s)**	Dr. Ramneesh Garg Dr Sheerin Shah
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Jaspal Singh (Professor & Head, Surgery)	Mr. A K Jindal (Member, Ethics Committee)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Assistant Dean Academics)	Dr. Deepinder K Chhina (Professor & Head, Microbiology)
Dr. Rajoo Singh Chhina (Dean Academics)	Dr. Neena Sood (Professor & Head, Pathology)
Dr. Gurpreet S Wander (Vice Principal)	Dr. Gurpreet S Wander (Vice Principal)
	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / ~~No~~

Dr. Sandeep Puri
Chairperson
Research Committee

Chairperson
Research Committee

Approved: Yes / ~~No~~

Prof. Arvind Malhotra
Chairperson
Ethics Committee

Chairperson
Ethics Committee

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	Dr Karan Singh Village Deoria, P/O Bhawalkheda Distt Shahjahanpur UP
2	NAME OF THE INSTITUTE	DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA
3	COURSE OF STUDY AND SUBJECT	MCh, Plastic and Reconstructive surgery
4	DATE OF ADMISSION OF COURSE	11/09/2019
5	TITLE OF THE TOPIC	Role of blood lactate measurement for flap monitoring

6 BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Flap reconstruction is used for coverage of defects throughout the various parts of the body. This type of reconstruction requires a patient in good general condition. The free flap failure rate varies between 2% and 5%. There are multiple causes: infection, dehiscence of sutures, compression or vascular thrombosis. Vascular thrombosis are the most frequent complications and represents 15-73%. The majority of these complications occurred within the first 24 postoperative hours. The salvage rate of postoperative vascular complications is between 0 and 100%.

However, despite best efforts, flap necrosis remains a dreaded complication of the surgery. Identification of adequate vascularity is paramount to prevent this complication. When a suspicion of flap compromise is suspected, immediate interventions can help salvage the flap.

The consequences of failure are often severe: higher risk of death, delay of combination therapy (radiotherapy, chemotherapy), functional sequelae, aesthetic results, psychological and social effects. The success rate is greater when salvage surgery is early. It is therefore essential to detect as soon as possible arterial or venous thrombosis.

Various methods of measuring flap viability have been proposed to recognize flap compromise as soon as possible. Currently clinical monitoring is the gold standard. It is based on color, capillary refill time and local heat of the flap. Many noninvasive or minimally invasive techniques have been developed to improve early diagnosis of complications of vascular thrombosis.

Surgeons rely on physical examination to assess the vascularity of flaps by measuring temperature, colour, capillary refill and pin prick. Several adjunctive measures have been proposed to aid the surgeon in his/her quest. These include the use of Doppler based instruments, tissue pH monitoring, skin temperature probes, tissue oxygen tension, near infrared spectroscopy, photoplethysmography, micro dialysis, flap

glucose assessment as well as the use of fluorescent dyes amongst many others. Each technique has advantages and disadvantages. The aim of our experimental study was to compare the clinical assessment and intracapillary glucose and lactate measurements during monitoring of free flaps.

Therefore in the present study, we propose the use capillary measurement of lactate for free flaps monitoring. This method of assessment of flap viability is simple, cost effective and requires little special equipment. It is more objective than traditional methods of flap monitoring such as observing colour, turgor or pin prick examination.

6.2 REVIEW OF LITERATURE

In surgery, some defects require reconstruction with microsurgical flap. This type of reconstruction requires a patient in good general condition. The free flap failure rate varies between 2% and 5% [1]. There are multiple causes: infection, dehiscence of sutures, compression or vascular thrombosis. Vascular thrombosis are the most frequent complications and represent 15-73% [2]. The majority of these complications occurred within the first 24 postoperative hours. The salvage rate of postoperative vascular complications is between 0 and 100% [3,4]. The consequences of failure are often severe: higher risk of death, delay of combination therapy (radiotherapy, chemotherapy), functional sequelae, aesthetic results, psychological and social effects. The success rate is greater when salvage surgery is early [5]. It is therefore essential to detect as soon as possible arterial or venous thrombosis.

Despite rapid development in the field of reconstructive surgery, one core issue that persists to this date is the inability to accurately predict the viability of a flap. Although many attempts have been made to elucidate elaborate as well as simple adjuncts to aid the surgeon in his decision making, the ideal technique remains to be found.

Creech and miller [6] proposed that the ideal technique for assessment of flap viability should fulfill the following criterion:

1) Simple and harmless to the patient.
2) Rapid, repeatable, reliable, recordable and rapidly responsive.
3) Accurate and inexpensive.
4) Objective and applicable to all kind of flaps.
5) Equipped with a simple display that could alert relatively inexperienced personnel to the development of circulatory impairment.

The most common technique used to check for flap viability is "Clinical examination". These may include all or a combination of the following:

1) Colour
2) Turgor
3) Temperature

4) Capillary refill time

5) Bleeding following pin prick.

Although these methods are cheap and repeatable, they have certain limitations. The appreciation of colour, for example, is dependent on ambient lighting conditions. The colour of the donor site may be different from the recipient site as well. Skin turgor is affected by hydration status. Surface temperature is dependent on many factors including blood flow and changing metabolic rate of the underlying muscle. Capillary refill time too has a wide variation amongst its users due to little standardization. Hence, these techniques have to be supplemented by other more objective and reliable methods.

Free-flap reconstructions are today a common procedure, whatever the type of flap. Despite this evolution, the success rate never reaches 100% in large series [7,8], mainly due to pedicle complications such as thrombosis, extrinsic compression, or kinking effects [9-11]. This failure rate remains a concern and could lead to serious functional impairment. Moreover, it is widely accepted that the prognosis of such complications is improved if they are treated early [1].

In addition to clinical examinations, surface or implantable doppler, spectrophotometry, laser Doppler, tissue oximetry, and tissue pH may be used to screen pedicle impairments. Even if clinical examination has many drawbacks, these screening tests tend to be expensive and complex procedures. Among them, microdialysis [12,13] retained our attention. Simplification could be done by measuring capillary lactate. This procedure is evaluated in the present study.

The free flap survival rate has been stabilizing, at 94 to 99%, but the rate of salvage surgery in treating impaired blood flow is poor, at 34 to 73% [7]. Over time, impaired blood flow becomes irreversible [14]. Leaving impaired blood flow untreated can result in serious complications such as massive bleeding due to ruptured sutures or spread of infection to the carotid artery, particularly in head and neck reconstruction. As such, evaluation of flap blood flow is necessary to detect abnormalities and perform salvage surgery immediately.

The evaluation method for flap blood flow often relies on the visual impression of a physician or co-medical practitioner. Patients who have undergone head and neck reconstruction often have a free flap in the oral cavity, which is difficult to observe, so visual evaluation of blood flow is difficult. Therefore, persons who evaluate blood flow need more training. This may be possible in a large facility but is impossible in a small facility. If standard parameters exist that reflect flap blood flow, we believe that diagnostic capability will not differ between institutions. In this study, we will identify numerical values that reflect flap blood flow.

Among the numerous evaluation methods for flap blood flow, a method that measures intra-flap glucose and lactate values using microdialysis has been devised [15-17]. Microdialysis involves the use of embedded catheter in the flap tissue (eg, skin, muscle, or fat) to measure the target substance and can be used for buried flaps; however, it requires professional expertise. Currently, the primary methods indicated for evaluating flap blood flow are visual examination and clinical findings such as those from the pinprick test [18]. However, these methods vary widely depending on the evaluator's experience and level of objectivity.

Furthermore, the pinprick test can only be used for accessible flaps [19]. Ideally, blood flow evaluation should be simple and objective with no variance due to occupation or experience. Despite various studies on flap blood flow evaluation methods,[20-23] no standard has been established yet because the methods use expensive instruments or ones that are complicated to operate. Recent reports have suggested that blood flow abnormalities can possibly be detected early through measurement of blood glucose and lactate values [24].

In 1998, Rojdmark et al [15] measured intra-flap blood glucose and lactate values to evaluate flap blood flow. In addition, Sorensen [17] used those values for free jejunum flaps. Most previous studies that measured blood glucose and lactate values inside the flap tissue used microdialysis [15-17, 25-27]. Microdialysis is a method used during surgery in which a catheter is embedded in the flap tissue (eg, skin, muscle, or

fat) to measure the target substance. This allows for continuous measurement and excellent objectivity, but the complicated procedure and need for professional management have been cited as having disadvantages [16].

By contrast, a study by Sakakibara et al [24] examined blood glucose values in free flaps with a simple measuring instrument. In 2014, another study examined the usefulness of measuring lactate using the same method [16]. The major advantage of the simple measuring instrument is its ability to measure quickly and easily.

Several reports described the effects of blood flow obstruction on blood glucose and lactate values. Heden and Sollevi [27] showed that tissue hypoxia caused lactate values to increase and blood glucose values to decrease at the same time during ischemia.

Setala et al [25] reported that blood glucose values decreased 2 to 8 hours before clinical findings emerged and lactate values increased 1 to 12 hours before the findings of congestion. They speculated that the tissue was in a transient anaerobic metabolic state until the post-reperfusion flap tissue adapted to the new perfusion pattern. Unlike lactate values, after the blood glucose values increased to higher than the upper limit for temporary decreases, they remained higher than the reference value.

Jyranki et al [26] also reported that the blood glucose value increased over time. The cause was not clear, but findings indicated that the intra-flap blood glucose value temporarily decreased when insulin was administered, suggesting that generally, it is easily influenced by the blood glucose value of the body[26].

The aim of our experimental study was to compare the clinical assessment and intracapillary glucose and lactate measurements during monitoring of free flaps. Therefore in the present study, we propose the use capillary measurement of lactate for free flaps monitoring. This method of assessment of flap viability is simple, cost effective and requires little special equipment. It is more objective than traditional methods of flap monitoring such as observing colour, turgor or pin prick examination.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To study flap capillary blood glucose monitoring as predictor of flap survival.

7.0 MATERIALS AND METHODS

7.1 SOURCE OF DATA:

A prospective study shall be conducted on 30 consecutive patients admitted in operated Department of Plastic surgery, Dayanand Medical College and Hospital, Ludhiana who fulfill the inclusion criteria and none of the exclusion criteria. The protocol was submitted to and approved by the Ethics Committee.

7.2 METHOD OF COLLECTION OF DATA

Inclusion criteria:

Study will be conducted on all the consenting patients who have undergone any type of flap surgery.

Exclusion criteria:

Patients under 18 and pregnant patients.

Flaps that do not bleed on pinprick will be excluded from the study

All diabetic patients and patients who are critically ill will be exclude from the study.

Included patients were informed about the study with a written document, and their signed informed consent was collected. Patients were allowed to withdraw from the study at any time. The surgical procedure was then performed. Arterial anastomosis time was defined as H0. At the end of the procedure, the skin paddle was left accessible for the Flap Prick assay and clinical monitoring. First postoperative examination of the flap immediately will be done after the end of the surgical procedure. It is standardized: Skin paddle colour and temperature, skin reperfusion time, and bleeding test with a prick. Measurements were made with two devices, one for capillary glucose (Accu-check1Performa, or OptiumTM Xceed), and the other for capillary lactate (Lactate-ProTM, laboratories Arkray). The blood drop required for these two devices was obtained with disposable diabetes lancing device or a 25G needle. Blood lactate measurement will be done at 0, 3, 6, 12, 24 and 48 hrs after surgery. Along with blood lactate measurments clinical evaluation of the flap will also be done at same 0, 3, 6, 12, 24, and 48 hrs. Blood lactate measurement will also

be done when ever flap will show any signs of deterioration in viability in between these intervals.

Results that showed as "Low" during blood glu- cose monitoring were considered as 1.0 mmol L _1, since they are lower than 1.1 mmol L _1. Results that showed as "Low" during blood lactate monitoring were considered as 0.7 mmol L _1, since they are lower than 0.8 mmol L _1. Biological and clinical data were systematically written in an individual register together with the time of examination.

OUTCOME

Final outcome of the flap and any intervention required will also be noted.

Post-operatively facial contour symmetry will be assessed clinically and patient satisfaction, subjectively in both the groups and a comparison between the two groups will be made on follow up visits (week1, week4).

Overall cost of treatment will be compared between the two groups.

STATISTICAL ANALYSIS:

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

Yes

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

ATTACHED HEREWITH

8.0 LIST OF REFERENCES

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PROFORMA

S No :

MRD. No :

NAME .:

AGE/SEX :

FATHERS/HUSBANDS NAME :

CHIEF COMPLAINT :

HISTORY OF PRESENT ILLNESS :

PAST HISTORY :

WOUND HISTORY :

Mode of onset:

Duration :

Associated disease :

LOCAL EXAMINATION OF WOUND :

Signature of Candidate

Signature of Supervisor

CLINICAL EVALUATION OF FLAP :

DURATION	0	1	3	6	12	24	48
COLOUR							
CAPILLARY REFILL							
BLEEDING CHARACTERSTICS							
TEMPERATURE							
OUT COME OF FLAP							

FLAP BLOOD LACTATE MEASUREMENT

DURATION	LACTATE LEVEL	OUTCOME OF FLAP
0		
1		
3		
6		
12		
24		
48		

Signature of Candidate **Signature of Supervisor**

BLOOD LACTATE MESUREMENTS WHENEVER FLAP SHOWS SIGN OF DETERIORATION IN BETWEEN THESE INTERVALS

INTERVENTION REQUIRED	DURATION AFTER SURGERY	SIGNS OF NECROSIS	BLOOD LACTATE LEVEL

FINAL OUTCOME

FLAP SURVIVED FLAP NECROSED

Complications:

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o.....
am willing to participate in the study **"ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

Name:

.....
Signature of the patient

Signature of Candidate

Signature of Supervisor

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"ROLE OF BLOOD LACTATE MEASUREMENT FOR FLAP MONITORING"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर